EXTENSION OF POLIOMYELITIS VACCINATION ASSISTANCE ACT

UNIVERSITY OF MICHIGAN
FEB 10 1956
MAIN READING ROOM

HEARING

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-FOURTH CONGRESS

SECOND SESSION

ON

H. R. 8704

A BILL TO EXTEND THROUGH JUNE 30, 1957, THE DURATION OF THE POLIOMYELITIS VACCINATION ASSISTANCE ACT OF 1955

JANUARY 24, 1956

Printed for the use of the Committee on Interstate and Foreign Commerce

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COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

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DEPOSITED BY THE
UNITED STATES OF AMERICA

EXTENSION OF POLIOMYELITIS VACCINATION ASSISTANCE ACT

TUESDAY, JANUARY 24, 1956

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met at 10 a. m., pursuant to notice, in room 1302 of the House Office Building, Hon. J. Percy Priest (chairman of the subcommittee) presiding.

The CHAIRMAN. The hearing will come to order.

This is a meeting this morning for the purpose of considering the bill, H. R. 8704, which is a very simple bill extending the present Poliomyelitis Vaccination Assistance Act of 1955 until June 30, 1957.

At this point in the record, and without objection, a copy of the bill will be printed, and also a letter from Secretary Folsom to the Speaker of the House with reference to the legislation.

(The documents are as follows:)

[H. R. 8704, 84th Cong., 2d sess.]

A BILL To extend through June 30, 1957, the duration of the Poliomyelitis Vaccination Assistance Act of 1955

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 2 and subsections (a) and (b) of section 6 of the Poliomyelitis Vaccination Assistance Act of 1955 (Public Law 377, Eighty-fourth Congress) are each amended by striking out "February 15, 1956" and inserting in lieu thereof "the close of June 30, 1957".

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, January 19, 1956.

HON. SAM RAYBURN,
Speaker of the House of Representatives.

DEAR MR. SPEAKER: I am enclosing for your consideration a draft of a bill to amend the Poliomyelitis Vaccination Assistance Act of 1955 (Public Law 377, 84th Cong.). The proposed amendments would extend the terminal date for the availability of funds appropriated for carrying out the purposes of the act, but would not otherwise modify the original program authorization.

The present terms of the act authorize the appropriation of such sums as may be necessary for making payments to States which have submitted, and had approved by the Surgeon General, applications for Federal grants. Sections 2 and 6 of the act, however, contain provisions terminating the availability of funds appropriated for this purpose on February 15, 1956. The Supplemental Appropriation Act, 1956, (Public Law 219, 84th Cong.) included an appropriation to the Public Health Service of $30 million for "grants to States for carrying out the purposes of the Poliomyelitis Vaccination Assistance Act of 1955. * * *"

The legislative history of both the enabling legislation and the appropriation for carrying out the purposes of the act indicates that it was the intent of Congress to authorize and initiate immediately a program of Federal assistance to States but to provide an opportunity for reviewing program developments

early in the second session of the Congress before completely implementing the Federal grant provisions of the act. Thus the objective of program review is the apparent reason for the inclusion of the February 15, 1956, time limit on the availability of appropriations, as well as the limitation of the initial appropriation to an amount sufficient to provide the several States with approximately half of the allotments indicated by section 3 of the enabling act.

On the basis of our experience to date, we believe that the enabling legislation provides an adequate base for program planning and administration, and we see no need for amendments other than the proposed extension of the time limit on availability of funds.

The progress of program development thus far has been contingent upon two key factors, apart from the availability of Federal funds: (1) the development and approval of State plans under the act, and (2) the rate of production of vaccine required for State vaccination programs, as well as for distribution through private channels.

The progress of State plan development to date has been very satisfactory. With one exception all States have completed, and had approved, their plans for vaccination programs, and have initiated their programs of vaccine purchase and distribution. As of December 31, 1955, Federal payments totaling $7,674,766 had been made to these States from the initial appropriations for this purpose. Further progress in the implementation of these programs will therefore be governed primarily by the availability of vaccine.

The volume of vaccine production and release during 1955 was limited but it is expected that the rate of production will now accelerate. Through December 31, 1955, a total of 16,390,608 cc. of vaccine had been released for sale to public agencies and commercial users (in addition to the 13,571,223 cc. of vaccine supplied to the National Foundation for Infantile Paralysis). Approximately 53 percent (8,750,000 cc.) has been reserved by the States for public agency purchase. It is presently estimated that by February 15 of this year the amount of released vaccine reserved for public agency purchase will aggregate approximately 15 million cc. This will be about one-fourth of the total required for implementation of the federally aided vaccination programs indicated by the allotment formula in section 3 of the Piliomyelitis Vaccination Assistance Act. The purchase of this amount of vaccine, together with additional State program expenses authorized by the act, will require payments to the States by February 15 of approximately half of the $30 million appropriated last year.

On the basis of present data on prospective vaccine production, we are recommending that the availability of funds appropriated pursuant to the act be extended through June 30, 1957. This should allow ample time for vaccine production to reach the required levels and for the available supply to be distributed and administered.

We shall appreciate it if you would refer the enclosed draft bill to the appropriate committee for consideration.

The Bureau of the Budget advises that enactment of this proposed legislation would be in accord with the program of the President.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

The CHAIRMAN. This act as we all know was passed late in the session last year, and it was passed with an expiration date of February 15, 1956. Therefore it is important that we take some action rather expeditiously.

We are pleased to have today Dr. Leonard A. Scheele, the Surgeon General, and others from the Public Health Service, to give us a report on the program conducted after the passage of the act and after the Department had ample opportunity to issue its regulations and get the program going in the States.

There was quite a bit of work to be done there. We realized that when the bill was passed in July, it would take some little time to organize the States and to issue the necessary regulations in the Department.

Without further preliminary remarks, I think that we shall ask Dr. Scheele if he will bring us up to date, at least generally on the program and its progress so far. I note that we have been furnished

here with quite a well-documented and indexed volume on the whole subject. I am sure that Dr. Scheele and others may refer at times to what is contained therein.

Dr. Scheele, we are very happy to have you as a witness, and you may proceed with any sort of statement you desire to make at this time.

STATEMENT OF DR. LEONARD A. SCHEELE, SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, ACCOMPANIED BY DR. LOWELL T. COGGESHALL, SPECIAL ASSISTANT FOR HEALTH AND MEDICAL AFFAIRS TO THE SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; DR. JACK HALDEMAN, CHIEF OF THE DIVISION OF GENERAL HEALTH SERVICES IN THE BUREAU OF STATE SERVICES; DR. JAMES SHANNON, DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH; AND DR. ALEX LANGMUIR, CHIEF OF THE EPIDEMIOLOGY BRANCH OF THE COMMUNICABLE DISEASE CENTER, ATLANTA, GA., OF THE PUBLIC HEALTH SERVICE OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. SCHEELE. Thank you, Mr. Chairman and members of the committee. I am accompanied this morning by Dr. Lowell T. Coggeshall, who is Special Assistant for Health and Medical Affairs to the Secretary of the Department of Health, Education, and Welfare. Dr. Coggeshall has recently joined the Secretary's staff, and he has come to be with us this morning.

Then I am accompanied also by members of my Public Health Service staff, Dr. Jack Haldeman, who is on my right, is Chief of our Division of General Health Services, in our Bureau of State Services and is responsible for the distribution program which has been carried on under this act.

We have Dr. James Shannon, who is on my left, Director of the National Institutes of Health, who is well known to you. He has been handling the problems of licensing and approval of lots of vaccine under the Biologics Control Act; and on my far right is Dr. Alexander Langmuir who is Chief of the Epidemiology Branch of our Communicable Disease Center at Atlanta. He has been responsible for the national poliomyelitis surveillance program, watching the use of the vaccine, safety and actual field use, and the problems of its value in terms of preventing paralytic polio.

We furnished you with a summary statement which is also before you, and the larger book with the brown cover is actually the compiliation of the references which are listed on the final page of the mimeographed summary report which brings the program up to date.

I am pleased to have this opportunity to appear before you in support of proposed legislation to extend the duration of the Poliomyelitis Vaccination Assistance Act of 1955. The bill, H. R. 8704, under consideration by your committee would extend the terminal dates for availability of funds appropriated to carry out the purposes of the act from February 15, 1956, to July 1, 1957, but would not otherwise modify the original program authorization.

The present terms of the act authorize the appropriation of such sums as may be necessary for making payments to States which have submitted, and had approved, applications for Federal grants. The act also contains a formula for allotting appropriated funds among the States. This formula includes three factors:

1. 33⅓ percent of the number of unvaccinated children under 20 years of age and the number of expectant mothers,
2. The cost of the vaccine, and
3. The ratio of the per capita income of the United States to the per capita income of each State.

Funds allotted among the States on this formula are available only for the purchase of vaccine. The act also authorizes an additional amount equal to 20 percent of this allotment to be available to the States for use in administering the vaccination program or, at the discretion of the State, for the purchase of vaccine.

In submitting their applications, States are required by the terms of the act to give the following assurances:

1. That the vaccine purchased with the grant funds will be used only to vaccinate children under 20 years of age and expectant mothers;
2. That no means test will be used to limit the eligibility of persons to receive poliomyelitis vaccination in programs conducted by public agencies;
3. That the State plan will be administered or supervised by a single State agency;
4. That the State will make necessary reports and provide efficient fiscal administration of its plan.

The act also authorized the Surgeon General to purchase vaccine for a State in lieu of cash payments at the request of the State. We are presently purchasing vaccine for 23 States.

The legislative history of both the enabling legislation and the $30 million appropriation which has already been made for carrying out the purposes of the act indicates that it was the intent of Congress to authorize and initiate immediately a program of Federal assistance to States but to provide an opportunity for reviewing program developments early in the second session of the Congress before completely implementing the Federal grant provisions of the act. Thus the objective of program review is the apparent reason for the inclusion of the February 15, 1956, time limit on the availability of appropriations as well as the limitation of the initial appropriation to an amount sufficient to provide the several states with approximately half of the allottments indicated by section 3 of the enabling act.

On the basis of our experience to date we believe that the enabling legislation provides an adequate base for program planning and administration, and we see no need for amendments other than the proposed extension of the time limit on availability of funds.

We have also been very encouraged by the demonstrated effectiveness of the vaccine. Experience during 1955 has shown that the paralytic poliomyelitis rate was more than four times greater among unvaccinated children than it was among vaccinated children in the same age group and same locality. This 1955 experience is all the more impressive because the great majority of children had received only

a single injection of vaccine. On the basis of this evidence we are confident that the vaccine is effective in preventing a very substantial percentage of cases of paralytic poliomyelitis.

The progress of program development thus far has been contingent upon two key factors, apart from the availability of Federal funds: (1) The development and approval of State plans under the act; and (2) the rate of production of vaccine required for State vaccination programs, as well as for distribution through private channels.

During the first several months of vaccine production, substantially all vaccine released was allocated to the National Foundation for Infantile Paralysis to carry out its program of vaccination for first and second grade schoolchildren.

As vaccine became available in excess of the current needs of the NFIP, each lot was allocated proportionately among the States by the Public Health Service on the basis of the number of persons in the current priority group in each State. Thus each State has received an equitable allocation of all vaccine released.

Through January 8, 1956, a total of almost 31 million net cc.'s of vaccine has been released. Of this amount approximately 13.5 million cc.'s were allocated to the NFIP. Substantially all of the remainder has been allocated among the States in accordance with the interstate distribution system currently in effect.

I might remind the committee parenthetically that as to this measure of quantity the cubic centimeter, 4 cc.'s make a teaspoon, to give you some idea of the volume. The recommended dose for a child is 3 cc.'s of the vaccine, spaced, the first 2 doses, approximately a month or 5 weeks apart, and the third dose given as a booster approximately 7 months after the second dose.

The States have a twofold responsibility in the total vaccine program. First, State health officers with the assistance of State advisory committees, have the responsibility for insuring equitable distribution of all vaccine within the States, including vaccine distributed through commercial channels. We have been very encouraged by the way States have responded to this challenging task. Although the procedures vary among States in accordance with local needs and preferences, the general pattern has been to allocate vaccine initially to counties and cities or to groups of counties on the basis of relative priority group population and then to make adjustments later in terms of demonstrated vaccine demand. The States report to us that on the whole they have received excellent cooperation from the vaccine manufacturers, pharmacists, druggists, and physicians on this difficult task and that their efforts have achieved an equitable intrastate distribution of available vaccine.

I might say, to our knowledge the manufacturers on a voluntary basis are working in this program and they have shipped vaccine entirely in accordance with the recommended distribution we have given them. There have been no variations in that.

Second, State health officers are responsible for the development and administration of vaccination programs financed by funds under the Poliomyelitis Vaccination Assistance Act.

All States except Massachusetts have had applications for funds under the act approved. We understand that Massachusetts, on the basis of a recent decision of its advisory committee, has now prepared

and submitted a plan which was received Monday of this week and is now being reviewed.

The vaccination programs planned and conducted by the States under the act vary in some details but they generally follow a common pattern. Most States have established advisory committees consisting of representatives of the medical and pharmaceutical professions and the general public. The States generally have made vaccine available to local areas where responsibility has been placed to arrange for administration of the vaccine. Most States are providing some vaccine purchased with Federal funds to physicians for use in their private practices. The majority of the publicly purchased vaccine, however, is being used in public clinics and the trend appears to be toward greater use in such clinics.

Through December 31, 1955, the States have reserved for public purchase approximately 8,735,724 cc.'s of vaccine or 55.5 percent of the vaccine released for interstate distribution. The cost of the vaccine reserved by the States for public agency purchase, together with the additional 20 percent cost of administration, would amount to approximately $8,250,000.

It is our estimate that between January 1 and February 15, 1956—the terminal date under the act—public agency purchases of vaccine as it is released and additional administrative expenses will call for additional payments of approximately $6 million. Thus it is possible that, except as States may obligate funds by issuing purchase orders before vaccine is released, only about half of the $30 million appropriation will have been spent before February 15. This lag in expenditures is the result of an inadequate supply of vaccine rather than because of a lack of need or desire for the vaccine and funds.

Based on the demonstrated effectiveness of the vaccine and the successful Federal-State cooperative action under the terms of the present act, we are recommending that the termination date of the act be extended to July 1, 1957. This extension, according to our best estimates, will allow ample time for vaccine production to reach the required level and for the available supply to be distributed and administered in accordance with approved State plans.

We therefore recommend your approval of the proposed extension at the earliest possible date.

The CHAIRMAN. Dr. Scheele, I have one question with reference to the NFIP program. I noted, I believe on page 4 of your statement, that through January 8 of this year a total of almost 31 million cc. has been released, and out of this amount approximately 13 million were allocated to the NFIP program.

How nearly is the NFIP program completed as far as your records indicate?

Dr. SCHEELE. It is very nearly completed. Dr. Haldeman has a fairly exact approximation.

Dr. HALDEMAN. Massachusetts will require about 150,000 cc.'s to complete their program there. Probably not over an additional 50,000 or so cc.'s will be required to complete the NFIP program.

The CHAIRMAN. That means, of course, that the total production very shortly will be allocated without regard to the NFIP program. It will have been completed.

Dr. HALDEMAN. That is correct, sir.

The CHAIRMAN. In all of the States?

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Dr. HALDEMAN. Yes, sir.

The CHAIRMAN. You mentioned, Dr. Scheele, that most of the State plans were fairly uniform. What could you say generally with reference to the 47 States that participated during the fall? Could you say that those programs were generally successful and effective in the States?

Dr. SCHEELE. Yes, sir; they have been very effective. Of course, we haven't been able to measure the effectiveness, and I am talking now about prevention of paralytic poliomyelitis in some of the States because the population at risk, and the population that had the vaccine, that is, in the age groups that had it, was rather small.

On the other hand, in a fair number of the States we have been able to get statistically valid data, and Dr. Langmuir and his staff have been working on that. We have had staff in the States to visit patients and study whether they were polio cases or not polio cases, and we might ask Dr. Langmuir to give a very brief report of the general value of the vaccine.

The CHAIRMAN. I think we would like to have that. Will you give your full name for the sake of the record?

Dr. LANGMUIR. Dr. Alexander D. Langmuir, Chief, Epidemiology Branch of the Communicable Disease Center of the Public Health Service, with headquarters in Atlanta.

Our major undertaking since April has been the poliomyelitis surveillance program. We have had over 40 professional workers assigned in collaboration with the States in attempting to do everything we possibly could to solve any problems, and to measure the effectiveness of the vaccine. It is most gratifying that consistently in every State where there has been enough polio to have any tests, we have favorable results. In all States where these studies have been made—it is more than 25—we have benefits of 50 percent or greater, as measured by comparing paralytic cases in vaccinated children with children of the same age group or just a little older or a little younger who were not vaccinated. In most of them the benefits are more than 75 percent, and they average out about 75 percent reduction.

So that, in spite of most of these being single inoculations given, the results have exceeded expectancy on the basis of our previous knowledge, and it gives us a great sense of assurance that with the larger supply of vaccine and broader use of the vaccine, we will have accelerated decline in the disease.

Dr. SCHEELE. There has been one very elaborate study, an additional elaborate study, done by the State of Massachusetts with the help of the National Foundation for Infantile Paralysis, I believe in that study, which has just been published within the last few days, they showed about a 60 percent effectiveness with one injection, because in that State they discontinued giving of vaccine after the season started.

They also, it is interesting to note, gave a clean bill of health to the vaccine with reference to its use in this rather severe outbreak of polio which they had in that State. Massachusetts, the eastern part of the State, was probably the hardest hit area in the country this year.

The CHAIRMAN. Dr. Scheele, assuming that there are no unforeseen developments, and unpredictable developments, would it be fair to say that the biggest problem from today on, as we develop this program, is the question of the production of adequate quantities of vaccine?

Dr. SCHEELE. Yes, sir, Mr. Chairman. I believe that this is our problem. The vaccine as we told the committee last year is a complex vaccine to manufacture. There are a variety of things that happen along the way, which can throw off any given lot, and these don't mean matters of lack of safety but just the very fact that they have to use living cells as part of the production and testing process.

Also, there is the fact that our manufacturers have limited facilities. They have to use a lot of their facilities just for the testing. We made life a little more difficult in the manufacture of this vaccine when we changed the quantities that they have to test. This has caused some slowness.

We expect this condition to improve rather rapidly now this year. In many instances, the manufacturers had to go back and utilize their testing facilities to retest the lots they had made previously when they had tested under the old standard, and we required their retesting under the new standard. This meant that in one instance the firm couldn't test new lots of vaccine which might come off the assembly line because they had all of their facilities tied up in the old testing.

The CHAIRMAN. Doctor, how many manufacturers are now supplying vaccine for approval?

Dr. SCHEELE. There are four at the present time.

The CHAIRMAN. Could you state those for us?

Dr. SCHEELE. These are Eli Lilly Co., Pitman-Moore Co., Wyeth Laboratories, and Parke, Davis & Co., which is in production but has not had a lot completed to the point of final approval yet. Sharp & Dohme hasn't submitted a lot yet. We are hopefully anticipating that they are going to very shortly.

The CHAIRMAN. There are a good many questions that I might want to ask, but I am going to yield to other committee members to ask some before I exhaust the field which is rather broad.

I had just clipped from my own hometown paper in Nashville a front page story quoting our County Health Officer as saying that the account is running low and the supply to be used will be exhausted by early next week unless renewed.

I wonder if that generally is true across the country; that they are pretty well up to the point of exhaustion of present supplies?

Dr. SCHEELE. This is a highly variable thing, and in some States they have some backlog, and in other States—Tennessee, and in Nashville they have been moving ahead rapidly with vaccination and I believe they are running out in Nashville today. I had a telephone call from some people down there.

The CHAIRMAN. They have moved along rather well in the program there.

Dr. SCHEELE. With a remarkable degree of interest in vaccination, and I believe someone down there told me as many as 90 percent of the families or parents were approving vaccination for the children in the current school program.

A few States have been a little hesitant to move ahead, or communities, very rapidly with their public programs because they wanted to get a little more backlog of vaccine. In other words, they wanted to be sure that they had the second dose in sight, to give to the children a month later. This has caused a bit of vaccine to stockpile in a few States, but it is a highly variable thing.

Some have moved ahead with public clinics and others are using most of the vaccine in private practice. There are variations from one to another. Generally speaking, we would say that we are about even with the board.

The CHAIRMAN. I have a few other questions on 1 or 2 of the provisions of the bill, as to how they are working in practical application, but I will reserve those for the moment.

Mr. Heselton, do you have some questions?

Mr. HESELTON. Not at this time. I might have later.

Mr. CARLYLE. Dr. Scheele, are you meeting with a degree of cooperation with the State and county officials throughout the country that has been expected?

Dr. SCHEELE. We have had full cooperation. It has been a very remarkable thing that in this particular instance, if everybody had operated as he usually operates in ordinary fields, each person would have done exactly what he wanted to do and what seemed best to him at the moment without caring very much about what the fellow next door was doing. In this case everybody has worked along on this voluntary system, the local officers and the doctors, on a voluntary basis. They are restricting the age groups to whom it is given—I am sure there are a few breaks here and there—but these are very minimum in terms of giving it outside the zero to 15-year age group that we recommend, plus pregnant women.

I mentioned earlier the cooperation of the manufacturers. In some instances they are permitting their vaccine to go outside their normal trade areas, and some of the manufacturers did not have a national distribution of their products and in this instance they shipped to all States when we told them that that is the way we would like that particular lot of vaccine distributed. That is to meet the State requests. It has been a remarkable demonstration of ability to work together on a voluntary basis, and hold the line very well without there being any rigid Federal controls or enforcement provisions.

Mr. CARLYLE. You spoke of the success of the vaccine in your statement. Do you feel that the success that has been derived from the shots meets your expectations?

Dr. SCHEELE. Yes, and it surprises us. We wouldn't have been surprised if it had been less successful because these measured end results are based by and large on single injections—that is, 1 cc.—and we have always assumed that we wanted to get in at least 2 before we would get a very good degree of protection. So we believe that we are dealing here with vaccine that is probably a little more potent than the vaccine that was used during the field trial period in 1954. Here the results are comparable with single injections to results in instances when 3 cc.'s were given.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. Dr. Scheele, this may be a little bit outside of the scope of your direct testimony but I was just thinking that Dr. Meyers, when we had our panel of eminent physicians, and I believe biochemists testified—they said there were certain impurities in the vaccine at that time and he said in his opinion they could be damaging to certain organs in the body.

I would like to ask you if those impurities in your opinion have been mostly removed by the biochemical processes or other processes?

Dr. SCHEELE. There are three sorts of things that I think were referred to as possible problems in that regard. One was the fact that penicillin was added to the vaccine as a preservative to hold down certain sorts of infectious material which might be there, which wouldn't necessarily be harmful to man, but there was the fear that the penicillin might cause sensitization. I think this was an unnecessary fear. Dr. Salk had done some very careful experiments on penicillin sensitivity before the field trial period and actually used penicillin-sensitive people. We have a situation in which the amount of penicillin is exceedingly small and upon standing in the vaccine it is mostly oxidized and we are literally dealing with no penicillin.

I think this fear came largely from folks who didn't know the scientific background of the penicillin in the vaccine. It is feasible to use other antibiotics for the same purpose, too.

Second, there was fear of sensitization because of the use of the monkey kidney cells at some particular point along the way. This, too, has been carefully explored by Dr. Salk, and had been ruled out as a problem of any consequence.

The third thing, I think, that came up during that panel discussion was the question of—and one that had come up in our own deliberations on the safety of the vaccine and on safety testing—whether the formaldehyde in activation might not, under circumstances of clumping of virus particles into masses, fail to kill adequately some of the particles at the center of the clump.

Well, this was recognized, and as we have modified from time to time the requirements of safety testing and so on, we have taken into account the necessity for being sure that that doesn't happen.

These things are very technical, but within the present amendments to the original requirements there are a number of steps, including some filtration steps, which are designed to assure that there is not the clumping. There are a number of other things that are done that also will effectively control that problem.

We believe that these objections, some partly theoretical in some instances, and some very real in others, are fully overcome in the vaccine as it is manufactured and tested.

As evidence of that, we point to the fact that probably over 10 million children by the end of December—and I am sure the number is much higher now because of clinics held during the first 2 weeks in January—have had this vaccine without untoward effects. I think that clinical trial is the real proof of the pudding. We have had no reason to believe that the vaccine, except for the earlier experience which you all know about, has played a role in the creation of polio.

This was a question in Massachusetts. There were some who felt that the vaccine used in Massachusetts late last spring may have actually played a role in triggering the very large epidemic they had. Well, some of the men who were on your panel and some of the men skeptical of the vaccine played a role in the study of that very problem in Massachusetts, and they came forth with a very positive statement to the effect that they could find no evidence that the vaccine had played any role in triggering of the epidemic in the State.

Universally, therefore, we feel that our experience to date shows that this vaccine is a safe product and a useful product for folks to take, and manufacturers can make it and we can determine that lots are safe. We feel it is worth using.

Mr. ROBERTS. Are we finding now that a good bit of the apprehension and fear on the part of the public has been dissipated?

Dr. SCHEELE. Yes, I think so. The public generally is not especially fearful. I think they see the positive results. I wouldn't say that some people who might otherwise have had the vaccine do not continue to carry some fear. There are those who oppose vaccination in any circumstance, and there are efforts made here and there to discourage vaccination. But this response in Tennessee of 90 percent, approximately, in those new programs since the 1st of January shows, it seems to me, that there is no great fear. That is as good or better than interest early in April before we had any untoward effects and when everybody was seeing this as a very great thing in the beginning.

Even in instances where we have a 70 or 75 percent acceptance in a school program we are doing probably as well or better than we do in a lot of other vaccination programs. I think that the answer to your question is that the fear is pretty well dispelled.

Mr. ROBERTS. Is it not true that during the course of your career you have become acquainted with other vaccines that have been introduced at various times? Are the fatalities in the use of the Salk vaccine comparing well with other vaccines, like yellow fever and similar vaccines that have been introduced in the past?

Dr. SCHEELE. I don't have very exact data on that, but in the case of yellow fever vaccine I think that actually there were more problems on that one at the beginning than we ever have had in the Salk vaccine. Of course, our goal is to have no problems.

Most vaccines have had some little difficulties in the beginning and I suppose these have stemmed largely from the fact that our state of knowledge at any given moment in terms of science is at a certain level, and in the best judgment of scientists and others, at a certain point we think we know enough about something, that everything is on the track. Then some unusual thing which was unanticipated and not foreseen—in this case things that came along probably in the process of large-scale production as against small-scale laboratory production—turned up.

Now, there were some problems in producing a field-trial vaccine. On the other hand, not a large amount of vaccine had been made, for the field trial in proportion to the large amounts that we were ultimately making as we moved to April 12 and beyond. In other words, we were sort of at the barrier in our scientific knowledge, and I think this probably has been our problem in the yellow fever vaccine and many others along the way. It leads one to philosophizing about whether one should hold off, or whether one should go ahead just like flying in a new airplane, or taking a new drug, or a new biological; there is a certain point where we do go ahead and pioneer and we do go ahead and use things.

We hope that we have all of the bugs ironed out, and sometimes we haven't. Then we correct them just as rapidly as we can. We don't like it to happen that way, but I suppose if our quest was for absolute security we would never take any of these forward steps. We would always be waiting for one more thing to happen along the way of scientific development.

So these are sort of weighed decisions, and in the case of medicine they are doctors' decisions, and as we said before, they are sort of like

the decision the doctor makes when he decides to operate or not to operate. You can't know the whole story of what is going on inside your patient, but you make a doctor's decision that it is in the patient's best interest to operate, and you do operate.

The doctor hopes to get a good end result, and he doesn't always have that good end result.

Mr. ROBERTS. Mr. Chairman, I know I am taking too much time, but I would like to ask one more question. What is the minimum age that generally is recommended by physicians at which injections should be made? I am trying to get at how young a child can be and still try this vaccine. What is the minimum age?

Dr. SCHEELE. The recommendation is that vaccination be given as early as a month or so of age.

In one of the studies, intensive studies under way, which has not been published in detail as yet, but which we have a preliminary report on—this work is being done at the University of Michigan in the department of pediatrics—it is shown that one begins to get increasing levels of immunity after 6 months or so, and probably for a child 8 months or 9 months, or 10 months or under, the important thing is that they have at least 2 injections. In other words, one shouldn't let them go by and expect that they will necessarily have what they should have with a single injection.

Mr. ROBERTS. Within what period of time?

Dr. SCHEELE. A month or 6 weeks. The time is not critical, actually, for the second injection. It is preferable to get it in 4 or 5 weeks, but if it is given in 7 or 8 or 9 or 10, it is maybe 95 percent as good or 99 percent as good.

There are advantages, however, in not giving them closer than a month. Dr. Salk found in his trials and others have found that if you give it as was given in the field-trial programs, say 2 weeks after, you don't get quite as much extra stimulus out of that second injection as otherwise one does with a little more delay. The body seems to put itself in a better position to respond to a second injection if it has been sort of reacting to the first one for a little bit longer time.

As you will recall, he also found that if one spaced the third injection off 7 months or more after the second, it was better than doing as we did in the field trials spacing them all 2 or 3 weeks apart. You just get more effect out of the vaccine.

So for the very young children, and I am speaking now of children 12 months or 11 months or 10 months of age or less, in line with present knowledge it is important probably that we make sure they get the second injection if we expect to have the fullest value from the first one last.

Beyond that it doesn't seem to make a great deal of difference. That is 1 year and on up. As we get older we have more and more natural immunity, and therefore we have less and less reason for having to have the extra boost that we get from vaccine.

Mr. HAYWORTH. Will the gentleman yield? I found instances in my district in which first dose had been given before summer vacation, and the second dose after summer vacation, which meant about 4 months of a lapse. I wondered if that would be considered good practice.

Dr. SCHEELE. It is not the ideal practice, but it is good practice. No one should not take a second injection because vaccine wasn't available,

or because physicians decided to delay during the peak season, let us say.

Actually, we are dealing with two things. We are dealing with the average of what will happen from a first injection in terms of development of antibodies and then a second injection to boost those still higher. Then we are dealing with what happens within the individual. Different individuals respond differently to all sorts of vaccinations, and we have some individuals who respond very little. Those folks will fall in the range of the 20 to 30 or 40 percent who didn't get much effect from their vaccine. They get paralytic polio.

Then we are dealing with other individuals, who got enough protection to not get paralytic polio when exposed. So we have these individual variations, and in the case of the child who got a second injection 4 months later, if he is one of the ones who reacts pretty well to this vaccine in terms of developing immunity, he may have gotten a lot more immunity out of the 2 injections spaced 4 months apart, or might have gotten more out of 2 injections spaced a year apart than another youngster of the same age with 2 injections spaced 4 or 5 weeks apart. So we are dealing with averages, and then we are dealing with what happens to each of us as individuals, in terms of how we respond.

I would say that this was perfectly good practice, and one that certainly is all right. We would prefer, of course, that the more ideal schedule of 5 or 6 weeks be used, but we have had problems of supply and then there has been the additional problem in some communities where there is a feeling that we shouldn't vaccinate during the peak season. Others feel that we can. This is again a physician's judgment.

Mr. HAYWORTH. Thank you.

Mr. ROBERTS. I yield the floor. Thank you.

Mr. DIES. I have no questions, but I do want to compliment the Department for their fine job. I have been impressed with the success of the program on a voluntary basis. It seems to me that that would be a very excellent example to be followed on many other programs; instead of trying to coerce and regiment and create all of the conflicts and jealousies and resentments, to be able to carry on a program of this magnitude is very fine.

This is a program of far-reaching importance, and to do it without any friction or conflict is wonderful. If there is any conflict, I have not known of any of it, especially in my State or my community. It demonstrates a very fine attitude and a high degree of efficiency.

The CHAIRMAN. Mr. Hayworth?

Mr. HAYWORTH. I have a couple of questions, Mr. Chairman.

Do you note any changes in cost of the vaccine, either Canada or the United States, between now and a year ago?

Dr. SCHEELE. We don't know of any in Canada. There may be a few pennies of change here.

Dr. HALDEMAN. The price which the manufacturer is offering is the same today as it was when they first put it on the market in April of last year.

Mr. HAYWORTH. That is $2.33.

Dr. HALDEMAN. It runs about 78.6 cents a cubic centimeter for public agency purposes. That includes average shipping costs and discounts. I believe it is $2.85 gross for a 3-cc vial.

Dr. SCHEELE. I might point out that a fairly large part of that cost is in the bottling. It is in the mechanics of bottling it. In fact, the fact that we have to have small containers, although in public programs we have 9-cc bottles, enough for 9 injections.

Dr. HALDEMAN. The price is $7.13 gross for a 9-cc. container, which amounts to 0.7922 per cubic centimeter. On the average, our experience in publicly purchased vaccine, brings that down, including shipment and discount, to an average of 78.6 cents a cubic centimeter.

The CHAIRMAN. Will the gentleman from Michigan yield for one question on the subject? Have most of the States requested that the Surgeon General or the Department purchase vaccine rather than turning over the funds?

Dr. SCHEELE. Twenty-three have requested that.

The CHAIRMAN. That you purchase the vaccine?

Dr. SCHEELE. Yes, sir.

Mr. HAYWORTH. Do you care to make any suggestions as to whether or not you think there should be further requests for this next year, or do you look upon this as the end?

Dr. SCHEELE. Well, you were thinking now of money, whether we would fill out the program. The President has indicated in his budget message, or budget for 1957, that we would proposed to ask for $30 million more. The program in the act, and as it would continue if the date line is extended, adds up to a program which would require approximately $60 million depending on the price. It might be down a little or up a little. That is to feel out the intention in the act itself.

So it is proposed if the act is extended to come in for a supplemental for approximately $30 million to comply with the intent of Congress in the language of the act as passed.

Mr. HAYWORTH. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Heselton, do you have any questions?

Mr. HESELTON. I would prefer to wait, Mr. Chairman.

The CHAIRMAN. There are some members of the full committee present, and if they have some questions we would be glad to have them asked.

Mr. BEAMER. I am very much interested, as I know the entire committee is interested, and I want to join our colleague from Texas in complimenting the Public Health Service; an excellent job has been done.

I have just two questions more or less in the form of statements, perhaps. You made some mention about the availability and the productive capacity. In other words, do I understand that the biggest problem, if there is any problem now, is whether or not the laboratories can produce a sufficient quantity; is that correct?

Dr. SCHEELE. That is right; a sufficient quantity so that one could, if there were a universal demand at a given moment, saturate that demand. Actually, we do anticipate that the demand will be saturated in due time, but it isn't quite as fast as some of us would like to see it.

There is a chart here on our production in this mimeographed report. You can see that, the heights of the columns. This was April. In April we had vaccine that had been made over several months' period earlier. Then we slowed things down because of the testing

and various things, and gradually we built up and then we dropped off again in October and November and December, and now we are expecting this to come up again in the months ahead.

Mr. BEAMER. I am especially interested, because I have been in touch with the two laboratories in my home State of Indiana and I rather gathered that they—and I think they are representative of the other laboratories—are in a position to increase their production if the demand is sufficient.

Is it true, perhaps, that they did not want to produce too much for fear that there might be some changes in the formula, or changes in processes, or changes in recommendations?

Dr. SCHEELE. I don't think this has kept them from producing more for the moment, because it has been made clear to them what is ahead, or what isn't ahead in the sense that there was some discussion of changing one of the strains of the virus, the strain No. 1.

This is a complex problem and one has to be real sure if one makes a change that the new one, that one substitutes, is in fact going to be effective in preventing paralytic polio. One has problems—the manufacturers have problems; can he mass-grow this particular new strain in his tissue culture. In other words, can he get a yield; does he have a manufacturable product?

These are complex problems, and are problems that are not solved easily.

I might say, also, that as we have understood better the problems of safety testing and manufacture we have gained an increasing degree of confidence in the fact that the present strain No. 1 is a manageable, good strain. We always have to keep in mind the fact that our end goal is to prevent paralytic polio, and we don't want to make a substitution down to something that is 10 percent effective and then find we might just as well have done nothing.

This is a problem, and I don't think that has held them down.

Mr. BEAMER. You think the manufacturer has a reasonable assurance that they will continue with this present strain?

Dr. SCHEELE. For a reasonable period of time ahead. We have given them no assurance that there will not be a strain change some time along the line, but this awaits more scientific research end results before it can be done.

Mr. BEAMER. This committee of ours visited other types of manufacturing plants and I think an invitation has been issued to this committee to visit one of the laboratories, and I would like to repeat if the committee ever have an opportunity to visit Indanapolis I think it might be very valuable for the committee members to become acquainted with these manufacturing processes.

The CHAIRMAN. The Chair did state that an invitation is on the chairman's desk to visit the Eli Lilly Laboratories, and we hope that we can set down a day and a night or more, if necessary, to make that trip before we get too crowded with committee schedules. We hope that we will be able to do that. I think that it will be helpful to the committee.

Mr. BEAMER. I merely repeat that because only last evening I talked over the telephone with some people in the Eli Lilly and they would be very happy to acquaint this committee, or the members of the Public Health Service if they wished to accompany us, with

their processes and their work and other things on which they are working.

I had one concern, Mr. Chairman, and I expressed it last year and I repeat it. It was in regard to the means test. I was fearful along with many others that perhaps by the use of the means test or elimination of the means test, many people who probably were unable to provide it for themselves might be left out without it because others would rush in and avail themselves of it.

I am wondering whether you find that anything has occurred in that particular thing?

Dr. SCHEELE. I don't think we have much that has come in that would make us intelligent on that.

Mr. BEAMER. I notice the President, in his message, was very specific on that point. He expressed the hope that the means test would not keep someone, or the exclusion of the means test would not keep deserving people, or shall we say the people who could not afford to buy it, from securing it.

Dr. SCHEELE. I think we could probably say that we haven't had instances come to our attention where this seems to have caused a problem. This is such a complex problem, it seems that even in things like the means test there are always 3 or 4 hurdles that are mixed up with this thing.

One of the hurdles here is the fact that we restrict age groups, and we recommend that they hold down to fairly tight age groups. Then you have a problem of whether you are going to have those who can't afford to have it, outside the age group, go ahead and have some of the vaccine ahead of the others.

We just haven't seen the problem, and I don't know whether he would be prepared to answer it, but I understand Dr. Bergsma, the health officer in New Jersey, is here to testify later representing the Association of State and Territorial Health Officers. Dr. Bergsma is an operating State health officer, and he might be willing to tell you what kind of experiences he has had in a State. He is in intimate contact with the communities in his State, and the use of the vaccine both commercially and in individual physicians overseas and in the State distribution for public clinics.

Mr. BEAMER. If I remember correctly, some witnesses expressed the concern that perhaps those with lesser means would probably be a bit reluctant to ask for it, and that was one reason we thought probably it might be eliminated. So they might be neglected.

I don't want to pursue this point.

Dr. SCHEELE. I don't think it has been a major problem.

Mr. BEAMER. It has worked out all right.

Dr. SCHEELE. There may have been some problems of this sort. I do know of one physician in Illinois who called me and he was holding off giving vaccine to a number of children who could afford to pay because he didn't want to dip into what he could have dipped into, namely, some of the State's supply of free vaccine, to give to those children; and he was personally trying to make sure that this situation of the more needy folks not getting it was the exception.

Mr. BEAMER. I think the doctor was expressing the concern that I expressed.

The CHAIRMAN. Mr. Hinshaw, do you have some questions?

Mr. HINSHAW. With the permission of the subcommittee. I am not a member of it but I am very much interested in the subject and I was unable to be present when the bill was finally passed in the conference report. I rather remember the bill as it was presented to the committee.

I notice in Stockholm, on the 21st to the 25th of November 1955, the World Health Organization met and a very distinguished group of biologists and physicians were present, including Dr. Langmuir of the Communicable Disease Center of the Public Health Service, who I believe is here today.

While there was a great deal in that report that ought to be given to the committee, and the committee ought to read the report before it does anything, there is one statement on page 36 of the mimeographed report of that group which interests me very greatly, and I would like to know something about it. It is as follows:

> For example: It has been confirmed by serological studies that where invironmental sanitation is still inadequate,
>
> presumably among the lower income groups and countries having low income generally—
>
> the disease is usually predominantly infantile, 90 percent or more of the cases occurring in the first 2 or 3 years of life, and almost everyone over the age of 5 is immune. Thus there is no point in vaccinating them. On the other hand, in countries where as many as one-third of all cases occur over the age of 15, it may be necessary to vaccinate persons up to the age of 40 or even older.

I presume that the Department has studied that subject and it is well aware of the experience in the United States. I would like to have a discussion of it.

Dr. SCHEELE. With your permission, I would like to ask Dr. Langmuir, who is our expert in epidemiology, and who was at that meeting, to answer your question.

Dr. LANGMUIR. This difference in age of cases of polio is an intensely interesting one and it relates not just to economic status but to size of family and to the opportunities for this infection to spread.

In this country we find in certain of the Northern States the age distribution of the cases tends to be in the older age groups, and upstate New York, for instance, in some epidemics at least, the average age is 10 or older. In many of our Southern States the peak age is still around 5. In many of the tropical countries, Egypt and India, for a long time it was felt that polio was nonexistent, and it was not recognized as such; but going in with laboratory studies. testing of blood and now a few studies really searching for the virus, we find it is there and it is universally present in these countries but that it affects infants under 1 year of age largely.

Careful studies have shown that some of these children grow up with signs of paralysis and we believe that many of them may actually die in infancy, and it not be recognized.

In certain islands some very nice studies have been made, like St. Helena, where polio does occur even in areas where the economic conditions are pretty primitive. There the disease affects all age groups back to the last time that polio was present. It is like the famous examples of Messel in the Pharoah Islands back in the last century. There is an enormous problem around age. In these countries where the disease is widespread, cases are confined to very young children,

and it would be futile to immunize the older ones because they already are immune. In areas like the Northern States of this country and like Scandinavia, it will be necessary probably to go well into the adult population.

Mr. HINSHAW. I asked that question only for the purpose of bringing out that any requirement nationwide, that this vaccine be given to a particular age group could be quite wrong, could it not?

Dr. LANGMUIR. Well, our reasons: We know we happen to be one of those countries which are fortunate economically and we do have our families live in circumstances that don't spread polio as they do in these areas that you mentioned, or that report mentions, and we do know that polio vaccine ideally should be given up into our older age brackets in the United States. Our only——

Mr. HINSHAW. Particularly in northern New York?

Dr. LANGMUIR. That is right, and our only purpose in restricting the age levels is a matter of matching the supply, the short supply, into the age groups of greatest risk, until such time as the supply can catch up with demand and need.

Dr. SCHEELE. We are not happy over the fact that we are restricting age groups. That is a voluntary method of being sure that in those Southern States, where the greatest risk is 1 to 5, and Northern States say 5 to 10, that those folks get it first. That is our only basis for having the restriction.

This is a temporary expedient to give the parent, in a sense, a guideline and to have him come into this voluntary cooperative program by saying "My child is 17 and my child needs the vaccine, but there is a little bit lesser risk than my other child or any neighbor's children who is 9 or 10. We will hold off."

This seems to fit in my own circumstances. We have three children. One was 8 and he got the vaccine, and we have one who is 15 and one who is 18.

In the District of Columbia, the decision of the doctors here has been to restrict it from 1 to 10. Our other two children aren't eligible, and we don't make any demand that they be vaccinated. That is the purpose of the restriction, and it is not because we don't recognize the need for going beyond that; and, as a matter of fact, the act recognized that. While it didn't take the age period 20 to 40, it did say zero to 20. That included pregnant women because they do seem to have somewhat greater risk than nonpregnant women.

Mr. HINSHAW. I am curious to know by what provision of law or the Constitution, or whatever, you are able to do this, to restrict the giving of vaccine to certain age groups which I would believe that everybody in the United States had a right to decide for himself.

Dr. SCHEELE. We have no constitutional basis for this. It is purely a matter of the experts getting together, and setting forth on paper, so to speak, what they think is an ideal use of the vaccine for the greatest public health good, and then beyond that it is a question of the parent demand, and physician action, controlled only by themselves. There is no compulsion in this, at any point.

A few States are actually vaccinating above 15 years of age, but only a few. We don't say, we don't deny them vaccine or money to purchase vaccine. It is purely a voluntary thing. And this has come about because, well, citizen groups and parent-teachers groups and national representatives of these organizations, and various medical

organizations have spontaneously and voluntarily arrived at these decisions that this will be the ideal program. Beyond that it is purely a matter of individual voluntary cooperation.

There is no constitutional provision for any enforcement of any of these things, and as I say, they are purely voluntary.

The CHAIRMAN. Actually, if the gentleman will yield, it would not be necessary unless there was compulsion. I think if it were a question of compulsion, then there would have to be a constitutional basis for it. But since it is not compulsory, and it is a voluntary program, it may vary in the several States. When the States call their own councils together, they agree among themselves what age groups within that State are most susceptible and therefore should be the first to be entitled to this vaccine under this particular type of program.

Mr. HINSHAW. I realize that, but the Surgeon General has mentioned that certain age groups are a part of State plans which are to be approved by the Surgeon General. I just wondered whether or not age groups actually were in the question as to whether or not the Surgeon General should approve of the plan.

Dr. SCHEELE. No, sir, we do not take into account the age group which the State indicates will receive the vaccine, except to make it comply with the law itself, which states zero through 20. They could come in with a State plan and say they wanted to give it to 18- and 19-year-olds, and we would approve their plan. Our approval of the plan is only on those things which are a part of the law. Beyond that our statement that it would be nice for them, or ideal for them, to restrict to the age groups at greatest risk is merely our bringing to them the advice of an advisory committee of outside people that that is the best practice for the greatest public health good. That is for the greatest effect on reducing paralytic polio. We wouldn't take it into account in disapproving State plans.

Mr. HINSHAW. Mr. Scheele, section 4 of the acts states:

> Provided that the Surgeon General may, for the purpose of assuring the most effective and equitable distribution and use of available supplies of poliomyelitis vaccine, establish categories of eligible persons to be accorded priority in receiving an opportunity for vaccination against poliomyelitis and so forth.

Now, what categories of eligible persons have you established?

Dr. SCHEELE. We have established only the broad category which is in the law; that is, zero through 20. We have never exercised anything further.

Mr. HINSHAW. Where is that in the law?

Dr. SCHEELE. Section 10 (b) (1). We have never used this provision which would have enabled us to indicate a narrower category than zero to 20, and used that in our decisions on State plans.

Mr. HINSHAW. Further down in the same page, on page 36 of this statement of the World Health Organization it says:

> In the present state of knowledge there are many questions which cannot be answered. In a country where the disease is practically restricted to early childhood, it is not yet known how effective the vaccine will be, nor is it known what effect vaccination will have on the epidemiological situation. Should it prove that mass vaccination will greatly reduce dissemination of poliomyelitis virus in an area, artificial immunity will not be reenforced by natural exposure, and the vaccinated population will be immune only for as long as the protection of the vaccine lasts unless reenforcing doses are given at regular intervals. There is at present no knowledge of the long-term effects of vaccination. The possibility must be considered that in such areas, the favorable balance between infection and immunity which at present exists may be upset.

I would like to have your comments on that.

Dr. SCHEELE. Again I am not an expert and with your permission I would like to pass that question to Dr. Langmuir, who is an expert.

Mr. LANGMUIR. This was a subject discussed at length among the group at Stockholm. One of the issues was the lack of knowledge available to use at that time about the effectiveness of the vaccine in different age groups.

You may remember that in the report at Ann Arbor, of Dr. Francis' study, there seemed to be a difference in the degree of protection afforded in 6-year olds versus 8- and 9-year olds. That has caused enormous amount of discussion among all of us interested in the problem as to how valid that one observation has been.

It is exceedingly difficult to get information this year regarding that subject because the vaccine was given only to first and second graders in very large and very narrow age range. We didn't have a larger number for observations, but the preliminary figures that I have seen from Massachusetts suggests that there is no difference between the 6-year olds and the older ones. This is not a complete report yet, but it is pertinent to this particular subject.

Mr. HINSHAW. Now, of course, we just pointed out that there are different conditions existing in different parts of the world.

Dr. LANGMUIR. That is very true. The worry that we had was that maybe the vaccine was effective only after some experience during the first 5 or 6 years of life. However, most of us, I would say, believe that the vaccine will be highly effective at all age groups.

The duration of the effectiveness of the vaccine is going to be the most crucial problem, I would say, facing us during the next 4 or 5 years. I see no way we can accelerate this measurement. You are going to have to wait and observe children who have been vaccinated and keep a close record on this and watch large numbers over a period of a number of years before we can get an answer to how long 1 or more likely 3 doses—the recommended procedure for Salk vaccine—will provide protection.

Mr. HINSHAW. We speak of Salk vaccine, Doctor, but there was a pre-April 12, 1955, variety which was preserved with merthiolate, and that was abandoned as a preservative, and subsequent to the trials; was it not?

Dr. SHANNON. Yes, sir. It was abandoned because the merthiolate was shown to have an affect on the effectiveness of the vaccine and destroyed its effectiveness for a time.

Mr. HINSHAW. It destroyed its effectiveness?

Dr. SHANNON. Yes.

Mr. HINSHAW. It destroyed its effectiveness and it also destroyed virus, too, I believe. Any virus that might remain active.

Dr. SHANNON. That is a question that some scientists will say "yes" and some say "no," but they will all say that the virucidal effect is very slight.

Mr. HINSHAW. It was contained in the report that Dr. Scheele made to the Secretary of Health, Education and Welfare, that it was antivirilogical, or something like that.

Dr. SHANNON. The report said that destroyed antigen.

Mr. HINSHAW. It also has an effect on the antigenicity.

Dr. SHANNON. Yes, sir.

Mr. HINSHAW. Of course, the vaccine used after April 12 did not contain merthiolate and hence the so-called tests that were made prior to that time by the stuff that contained merthiolate are not necessarily applicable to the conditions subsequent to April 12; is that not true?

Dr. SHANNON. In the first place, sir, a number of the vaccines do contain merthiolate fill. It was found that if one adds merthiolate, then if one adds a complex organic compound called Versene, it precludes the effect of the merthiolate on the antigenicity. The bulk of the vaccine that has been used, as it so happens, since April 12, has had merthiolate in it. It so happens that the largest manufacturer has merthiolate in its vaccine.

Mr. HINSHAW. Then there is a question as to its antigenicity, is there not?

Dr. SHANNON. No, sir; with the other property it is not effective.

Mr. HINSHAW. How can you tell, because you have only had less than a year, or half a year, to find out?

Dr. SHANNON. It has been tested, sir.

Mr. HINSHAW. How can it be tested?

Dr. SHANNON. In monkeys.

Mr. HINSHAW. As to whether or not the antibodies are set up?

Dr. SHANNON. Yes, sir.

Mr. HINSHAW. How about in children?

Dr. SHANNON. There have been a number of studies on antigenicity in children. They have not been published yet, nor will they be published until the end of this compilation of this season, but each of the manufacturers has conducted tests on antigenicity himself in support of his own product.

Mr. HINSHAW. It states in the World Health Organization report that it is not known how long the vaccine will be effective, nor in what degree antibodies are set up, and so on.

Dr. SCHEELE. That is true of any of our vaccines, for other things. Those are differences in the individual patient response to vaccine. On this matter of duration of immunity, this refers to how long we will keep the immunity once we have established some from the initial vaccinations. Dr. Salk has been following his original children in Pittsburgh, and these are the children who have had vaccine the longest time, as far as past history is concerned, and as of 6 or 8 months ago he had children who had carried their antibodies against all types pretty high for 30 months.

What we are dealing with here, this thing that Dr. Langmuir is talking about, are those of 4 or 5, or 6 years from the time of vaccination. That is a question of whether, having had 3 injections, the youngster goes on for 7 or 8 or 10 years without having to have another booster, or whether this is like typhoid vaccine or like smallpox vaccine where after certain intervals we take another booster to sort of lift us up again to a high level because we have dropped off some.

We don't know today whether we will have to give another booster at the end of 3, 4, or 5 years. That is the unknown. But that isn't a serious problem. That will be determined as we go along and if it is like other vaccine and requires boosting, we will recommend boost-

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ing. But that would not have been an excuse for not using the vaccine until we had the answer 4 or 5 years from now.

Mr. HINSHAW. My attention has been called to the Journal of the American Statistical Association for December of 1955, in which the first article by a man by the name of K. A. Brownlee, of the University of Chicago, concerns statistics of the 1954 polio-vaccine trial.

There he summarizes it by saying—

59 percent of the trial was worthless because of the lack of adequate controls. The remaining 41 percent may be all right but contains internal evidence of bias in favor of the vaccinated. There was hope that an independent trial could be run in Great Britain under the auspices of the Medical Research Council, but this has been abandoned since they concluded that the vaccine was too dangerous.

What comment do you have on that?

Dr. SCHEELE. Starting at the end, the vaccine being too dangerous, they did decide that they didn't want to make vaccine with the Mahoney strain and they have been working to develop a vaccine with another strain, but they still will face a field trial with that to find out whether or not it is effective. And that is apparently going to happen.

They have announced that they will have a vaccine for us this spring.

Now, on the matter of the reappraisal of the field trial material from a statistical standpoint, I am not a technician in the field of statistics, and again Dr. Langmuir is, but I would only say this: It is conceivable that there may be some elements of statistical correctness in their comments. In at least a part of the trial, they do suggest that the statements about the value of the vaccine were correct; to support the findings of the group in 1954 is our 1955 experience. In other words, those findings in 1954 are reinforced now by a much larger experience in 1955.

Granted that the 1955 experience was not a carefully controlled experience and we are beyond the point in the United States as far as this vaccine is concerned, of having other than small studies which show us things which we will use in extrapolating but will not give us the sort of thing that the 1954 thing did.

With your permission, Dr. Langmuir may care to comment on that appraisal of the 1954 trial.

Dr. LANGMUIR. Dr. Brownlee's article is an exceedingly interesting one because he now points out in rather forceful language some of the problems that were pointed out to Dr. Francis in the design of his study. Namely, it was that if he were to do a study where he gave vaccine to second-grade children and then used first- and third-grade children as his so-called control, that this would not be a well-designed study. It would not be a good control because, first- and third-grade children are different in a great many ways from second-grade children.

Actually, this was a discussion that I participated in with a good many others. A group of State epidemiologists brought pressure to bear on Dr. Francis and, as a result, the placebo study where they gave first-, second-, and third-grade children ultimately vaccine, or a salt solution without vaccine—and no one could tell the difference except in a carefully secured code—was added to the program.

This was a very difficult thing to do in the scale on which it was carried out. Dr. Browlee's point, I think, is entirely valid insofar as he says the placebo study gave a more definitive answer.

I actually differ with Dr. Brownlee in his argument that the first grade controlled versus second grade gave no value at all. I believe strongly that it gives strong supporting value. I am actually in correspondence now on this very question of carrying on some letter to this journal to call the attention of Dr. Brownlee to the fact that the observed control study is supporting. I have an analysis that is involved, but I think it does support the conclusion that it helped although it is not as good as the carefully controlled placebo study.

Mr. HINSHAW. Dr. Brownlee states in this article, and on page 1009:

> The second place where the data of the report made plain for strict randomization is in table 2-B, where, in the placebo areas, those receiving the placebo had a significantly higher rate (57 per 100,000) of paralytic polio than those not participating in the trial (36 per 100,000). A sample survey (p. 13) established that the nonparticipants belonged to lower socioeconomic groups than the participants.

Dr. LANGMUIR. This is well documented, and it was a major issue that the advisory committee to Dr. Francis considered repeatedly.

The CHAIRMAN. Let me add further, if the gentleman will yield, that that subject was very exhaustively discussed during the panel discussion before the subcommittee last year——

Mr. HINSHAW. I read that, but this is a statistician's report, and not a doctor's report, as of December 1955, and it was subsequent to the time of the panel report to this committee and consequently they ought to have known more about it.

Now, I am also interested in the fact that the editor of the American Association of Public Health Physicians Bulletin charges that a double standard of reporting was set up in your division in contradistinction to the National Office of Vital Statistics. He claims that the way of reporting the cases after April 12, the method of reporting, has been very faulty.

Now, has any study been made of this method by a competent disinterested person, or group?

Dr. SCHEELE. That particular paper is a very complex one. We have a double standard, but there is nothing wrong with this double standard. In our normal reporting of communicable diseases physicians are required by local ordinance or regulation of local boards of health, and there are certain requirements of State boards of health that certain diseases be reported and they are reported based on the physician's judgment of his case, and our National Office of Vital Statistics assembles those.

They are the best compiliation one gets on a nationwide basis of what the incidence of disease is, and just like our death data, it is the same thing. Probably our deaths from heart disease are off some percentage plus or minus, because some doctors may sign a patient out that they haven't seen much of and decide it was heart disease when maybe it was some other thing that was primary.

The other standard is the standard Dr. Langmuir has set up for very careful studies in which his staff and other members of the staff of local and State health departments actually investigate the individual cases. When a case of polio is reported, there is a visit to that case and a very

careful effort is made to determine whether it is polio or isn't polio, and a case which might turn up in the national statistics of what is happening month by month as a polio case doesn't get wiped out in a rereporting system as it might get wiped out in Dr. Langmuir's careful scientific study when we discover it was the measles and encephalitis and you couldn't isolate virus from the patient.

That is the double standard. There is nothing wrong with this double standard.

Dr. Langmuir may care to extend my comment.

Dr. LANGMUIR. I would like to very much, indeed, for the record. The issue there was over our use of a device called accepted cases.

Mr. HINSHAW. I understand.

Dr. LANGMUIR. And the charge is that we refused to accept certain definite cases with a view of minimizing any problem that might be involved there. The contrary is what happened. We did not refuse to accept any case except where the total information presented cast a serious doubt as to the diagnosis, because we were sending to all State health officers information regarding these cases occurring among vaccinated children, and these became a matter of record, and a great many people were concerned with them, and all we asked was that we receive enough information so that we had reason to think that we wouldn't be withdrawing the record a day or two later.

We left the responsibility for the diagnosis in the hands of the State health officer or the State epidemiologist, his deputy, and asked that the significant dates of when the onset occurred and when the vaccine was given, and when paralysis first occurred and where that paralysis occurred, be provided to us before we published this information. That was the basis of accepting cases.

Actually, many of the cases that we accepted were later withdrawn as laboratory results came in.

Now, although we haven't gone to an independent kind of check, we have gone back to each of the States and submitted a list of our records and asked them to give us a verification of them and we will have for publication a complete list of these cases. That will be done soon.

Mr. HINSHAW. The charge was made, also, that the reporting of accepted cases delayed the statistic so that it actually was of little value.

Dr. SCHEELE. One has to have a volume and we have never felt, Dr. Langmuir has never felt, that, as a scientist—and he is a statistician and a physician—he would ever be in a position to publish fairly definitive end results, or quite definitive end results until January or February of 1956. This has been our statement all along. We have made it very clear that our comments or his comments and his appraisals in the fall and in the winter were very preliminary, and they were guide materials to give us some little rough index of where this ship was going.

That is whether we should stay enthusiastic about the vaccine, or be a little less enthusiastic. They were not intended to be finally definitive, and it is even recognized that they will never be finally definitive because we are beyond the point where the truly carefully controlled scientific study can be done.

We are going to have to deal in crude data and crude end results. But there is nothing wrong with that. That is the way we make progress.

Mr. HINSHAW. Well, have you had a critique of these methods made by your statistical division in Washington?

Dr. SCHEELE. Yes; we feel that it is all right.

Mr. HINSHAW. And the report of the statisticians to you in Washington is that the method was good?

Dr. SCHEELE. Yes; that Dr. Langmuir's method was good and I don't know what other method he could have used to take bias out of what he was trying to do. He was trying to operate scientifically as against crudely.

Mr. HINSHAW. Mr. Chairman, I think that this bulletin of the American Association of Public Health Physicians, which after all is quite an extensive organization, I would assume—it is the public health physicians—this editorial by its editor, Dr. Herbert Ratner, of Chicago, would bear reading by the committee because it contains much to challenge anything that the Public Health Service would have to say and much that other people would have to say. It is a compilation, I would take it, of the challenges that have been made to both the NFIP and the PHS in this matter.

I have noted a number of articles in medical journals that would indicate clearly that this committee ought to make a very careful study of this matter, and I think, of course, for the present there is no particular objection to extending the legislation but as far as making any additional appropriations are concerned which I understand is not necessary because a very small portion of the original appropriation has been expended—what amount has been expended?

Dr. SCHEELE. Approximately $8 million to $9 million.

Mr. HINSHAW. The last figure that I had was $5 million.

The CHAIRMAN. May the Chair inquire if the gentleman from California is questioning the safety of the vaccine?

Mr. HINSHAW. Yes; because it has not been adequately tested.

The CHAIRMAN. Of course, it seems to the Chair that we have only had 1 year or less than a year of operation so far in the use of it. That experience of 1 year will give us a far greater opportunity to evaluate than even the field trial, because it is on a much greater scale, and involves a great many more people who have obtained the vaccine.

It would seem to me that an evaluation of the year, let us say, from April to April would give us a much better opportunity to evaluate than simply to go back to the field trials.

Mr. HINSHAW. Mr. Chairman, this does not involve the methods used in the field trials. This comes into a question of what amendments have been made to the minimum requirements for the vaccine since April 12. There have been four such amendments made to the minimum requirements.

The last one was a quite important one because it changes the method of manufacture very importantly, to require certain filtrations. Presumably filtration is good, but I think some experience should be had because under the previous method, as stated in the Surgeon General's report to the Secretary of Health, Education, and Welfare, under that situation, unaccountably live virus appeared in certain lots of all of the manufacturers. It was not just one.

Dr. SCHEELE. Well, that was a variable thing, and there was one manufacturer that didn't have any come through.

Dr. SHANNON. The point that may be overlooked, however, is the fact that the adding of additional steps was designed to increase the

ability to produce consistent lots, but proper safety testing would always have kept any given lot from being released and harming people.

In other words, the vaccine released—there is a difference between vaccine released and vaccine manufactured.

Mr. HINSHAW. You do not mean that exactly, do you, Doctor?

Dr. SHANNON. I am talking about our safety standards, and our testing standards after their modification.

Mr. HINSHAW. That is what I am talking about, too. You do not mean that because you know that the cortisone test was instituted some time in November.

Dr. SCHEELE. Well, it is the belief of our scientists and our advisers that the safety tests, as we modified them back in the spring were adequate safety tests. Now, we have been putting improvements on them, yes.

Mr. HINSHAW. I admit that they were thought so at the time that they were issued, but the fact that they were amended indicates that they were found not to be adequate, were they not?

Dr. SHANNON. They will be amended many times in the future, like all products. We are always achieving—we know as we learn more how to do things better and our monkey test was not as satisfactory as it might have been and we made the monkey test an additional test that was more satisfactory. Our tissue culture test was a highly sensitive test.

Mr. HINSHAW. Mr. Chairman, it said that the injection of cortisone into the monkey, I believe it is the left leg according to the minimum requirements, makes the monkey something like 25 to 100 times more susceptible to the disease than he would normally be. Consequently any live virus which might prevail in the vaccine would be from 25 to 100 times more easily found than before. That requirement was issued, I believe, on the 11th day of November, was it not?

Dr. SHANNON. Yes, sir; this was. But I think that this fact must be viewed against a larger group of facts. When the tissue culture test was expanded to include much larger volumes, it acquired so much greater sensitivity than the current monkey test, that is, the monkey test then current, that there was some question as to whether or not the monkey test should not be abandoned.

It was decided more or less that if it could not be increased in sensitivity so as to bring it up and compete with the more sensitive tissue culture test, it would be abandoned.

What has happened is that the monkey test has now been brought to the point of sensitivity where it is competing with the tissue culture test. This actually is a development that goes back beginning in June or July, where there have been progressive attempts to modify the monkey test. It was put into preliminary trial with the manufacturers in September, and put on a semiofficial base in October, and further modified in November, after it had sufficient trial in the hands of the manufacturers for us to realize that this was now a stable test that could be carried on from here on.

I think that if the monkey test were the only safety test, then this would be of tremendous importance from the standpoint of excluding vaccines containing live virus, but since it is a supplementary test, although it is an important advance, it has lesser importance than would otherwise be the case.

Mr. HINSHAW. In another article, and as I say I read quite broadly on this subject, Mr. Chairman, but another article contained in the New England Journal of Medicine for last September, which was before the last amendment to the minimum requirements, stated—

As a guide to the manufacturer these standards are defined in minimum requirements. If the product is a killed-virus vaccine, like the formaldehyde-inactivated poliomyelitis vaccine, these product standards require that no living virus be present—

That is not that a chance be run, but that no living virus be present—

in any of the human dose volumes contained in the total lot volume. It makes no exception that allows for a chance infective dose or even a so-called subclinical infective dose. If the proposed method cannot give this degree of accurance, it is not an acceptable method. This is particularly true when the agent is a suspended particulate substance—

to which you referred just a moment ago when you spoke of the vaccine clumping—

viral or bacterial, in contrast to diphtheria toxin used for toxoid production which is a substance in solution. When the efficacy of each step in production or its reproducibility is doubtful, ultimate safety can be assured only by testing of the entire lot volume in an in vitro or in vivo test equally sensitive to the human being who previously has had no contact with the etiologic agent. This necessity would make the production method totally impracticable.

In my opinion, the formaldehyde-inactivation method as presently carried out cannot result in a vaccine that meets these prescribed standards for product safety for the reasons just enumerated.

Now, that gentleman, I understand, was 30 years in the Public Health Service, and in charge of the biological controls. He was Dr. M. V. Veldee, now chairman of biology at Stanford Research Institute. I assume he is a competent person.

Dr. SCHEELE. Yes, sir; he is competent.

Mr. HINSHAW. I think, Mr. Chairman, in view of all of these challenges that have been made, I believe that a serious study should be made of this whole subject.

The CHAIRMAN. May the Chair agree that this committee has never given up any idea of making a serious study. We have continued on it.

I think perhaps we made the most serious study last fall when we got 15 of the top experts in the country for a 2-day session, both morning and afternoon, and we made the most serious study possible of not just patting the committee on the head, but I think we made the most serious study of it at that time that has been made by any group other than those who are constantly on the job in the various departments.

I want to assure the gentleman from California that the committee will make a completely serious study and I appreciate the gentleman's contribution.

Mr. HINSHAW. I am quite interested in this subject, and I am only sorry that I can't serve on two subcommittees.

The CHAIRMAN. That is the regret of the chairman, also.

Mr. HINSHAW. I am neither a physician, a biologist nor a microbiologist; I am a civil engineer. I say that although I have not practiced civil engineering for a very long time. But nevertheless, I should remark that the evaluation of this material, the type of which I have presented here, cannot be made by this committee, and I think that I am as competent to say that as anybody.

It can only be made by really competent people, and people who are not in any way connected with any of the projects that now exist, is that not true?

Dr. SCHEELE. Yes, sir, and we agree fully with that principle and that is why, in the conduct of our affairs in the Public Health Service we have turned to the Nation's top virologists and especially to its top virologists who know polio, for our advice. That is why I think other governments have done the same thing.

It is interesting that others are now accepting the concept, the British have accepted the concept that one can inactivate polio virus with formaldehyde and their new vaccine coming up is a Salk-type vaccine, and other governments on the advice of virologists are doing the same thing, so we fully agree that the top experts who know the field are the ones who should be the ones to review these things.

I would point out that even today there are, as there were when the committee had its hearings, some differences of opinion among top scientists. Some of these men may not be as expert on viruses as others and some are highly expert. We have, however, it would seem, the bulk of them, the majority of them, those who have done the most research in the field, agreeing that we are moving along the proper lines and we do have safe vaccines, and that we have effective vaccines.

Mr. HINSHAW. Of course, the safety of it, or the testing for safety was greatly enhanced when it was discovered that cortisone being given to monkeys increased their susceptibility by 25 to 100 times or something like that. Consequently, we might explain by that method the slips that were made by the manufacturer is not in violation of the minimum requirements, I believe, in any case; is that right?

Dr. SCHEELE. No; in studying the protocols of the manufacturers we didn't discover any instances in which they didn't comply or in our study of the plant.

Mr. HINSHAW. And your report, which states that unaccountably some of these live virus appeared in the lots of all manufacturers, is an accident which can only be explained by not sufficiently sensitive tests being placed in the minimum requirements; is that not right?

Dr. SCHEELE. We didn't say that virus had turned up in lots of all manufacturers. That wasn't accurate.

Mr. HINSHAW. I think it was five manufacturers, then, I believe; is that correct? I think it was that none of the vaccine of another manufacturer was used in the market.

Dr. SHANNON. I would like to clarify one point, sir. In the five manufacturers who were distributing vaccine at the time, I believe the report stated that live virus was found in those vaccines at times which one would not have expected them to be there. But if one talks about vaccine that was distributed and released, vaccine from all five manufacturers was very extensively tested by a group of collaborating laboratories, and live virus was only found in some lots of the single manufacturer.

Mr. HINSHAW. These tables contained in the Surgeon General's report deny that.

Dr. SCHEELE. That was a subsequent report which reported the tests of blind samples of vaccine from all manufacturers; incidentally, cortizone tests were used on those.

Mr. HINSHAW. Mr. Chairman, this thing is just too confusing. The subsequent tests which we have heard of and which has not been

published, was made by the Department. It shows something else. The tables contained in this report made by the Surgeon General to Mrs. Hobby state, I believe—and I would have to find the page in order to clear the point—that five of the manufacturers had lots in which live virus was found.

Dr. SHANNON. They were not released.

Mr. HINSHAW. No.

The CHAIRMAN. I think a public statement has been made of those subsequent tests.

Dr. SCHEELE. Those are contained in the reports that we have given the committee.

The CHAIRMAN. And I know we received a press notice to that effect. That was about those subsequent tests.

Mr. HINSHAW. Well, the test data earlier is contained in this report and anyone can examine it.

The CHAIRMAN. That is true, but there was also public notice made of the subsequent tests.

Dr. SCHEELE. That was reported in the report on the Cutter Laboratory and the supplemental report on the Cutter Laboratory vaccine and these relate to tests of vaccine that had been released by us. It was not to the other experience which was the total manufacturing experience of each manufacturer.

Mr. HINSHAW. Were the monkey tests made on all lots of vaccine that were shipped out and used by the public?

Dr. SCHEELE. Not by us on every one. They were on substantial numbers.

Mr. HINSHAW. Well, this record in here shows that they were very rarely made. Actually, the protocols were used.

Dr. SCHEELE. That is correct in the release of the lots of vaccine; that is correct.

Mr. HINSHAW. Mr. Chairman, I think we need the advice of disinterested people in this confusing subject.

The CHAIRMAN. We will do what we need to do. Do you have any further questions?

Mr. HINSHAW. It is getting late, and I don't want to take all of the time.

The CHAIRMAN. Mr. Heselton, a minority member of the subcommittee, has not had a chance to ask questions yet.

Mr. HESELTON. First, I apologize for not being better prepared to ask the questions I had in mind. It is my fault, I should have known this hearing was scheduled for today, but I did not.

It so happens that within a matter of days, as the witnesses have indicated, the Massachusetts Advisory Committee indicated its approval of the program. It was only last Wednesday that Governor Herter sent a message to the legislature in that connection.

May I inquire, Mr. Chairman: Are witnesses here this morning in connection with testimony of the State officials?

The CHAIRMAN. The Chair wanted to inquire at this point, since it is noon, and it is the understanding of the chairman that there is no legislation on the floor this afternoon, if it would be convenient to hold a session at 2 o'clock this afternoon?

Could you be here, Dr. Scheele?

Dr. SCHEELE. Yes; I can be here.

The CHAIRMAN. Is Dr. Bergsma in the room? Can you be here this afternoon?

Dr. BERGSMA. I can.

Mr. HESELTON. Unfortunately, Mr. Chairman, there is rather an important meeting of a committee of the Massachusetts delegation which is scheduled for 3:30; but I would like to be present during as much of the testimony here as I can.

Would it be agreeable to the Chair that we resume at 2? I will let you know when I have to leave?

The CHAIRMAN. I might say, since the gentleman did not get his questions in this morning that he would be recognized first at the resumption of the session at 2 o'clock, in order that he might finish, if the other meeting is scheduled for 3:30.

Mr. HESELTON. I have a few questions I would like to ask.

The CHAIRMAN. With that understanding, then, the committee will stand adjourned until 2 o'clock.

(Whereupon, at 12 noon, the hearing was recessed to reconvene at 2 p. m. the same day.)

AFTER RECESS

The CHAIRMAN. The subcommittee will come to order.

When we adjourned this morning, Mr. Heselton was prepared to ask some questions of Dr. Scheele and others.

You may proceed at this time, Mr. Heselton.

STATEMENT OF DR. LEONARD A. SCHEELE, SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, ACCOMPANIED BY DR. LOWELL T. COGGESHALL, SPECIAL ASSISTANT FOR HEALTH AND MEDICAL AFFAIRS TO THE SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; DR. JACK HALDEMAN, CHIEF OF THE DIVISION OF GENERAL HEALTH SERVICES IN THE BUREAU OF STATE SERVICES; DR. JAMES SHANNON, DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH; AND DR. ALEX LANGMUIR, CHIEF OF THE EPIDEMIOLOGY BRANCH OF THE COMMUNICABLE DISEASE CENTER, ATLANTA, GA., OF THE PUBLIC HEALTH SERVICE OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE—Resumed

Mr. HESELTON. I would like, Mr. Chairman, to confine myself to certain questions which I think are basic but, unfortunately, because of the experience of Massachusetts with which I am somewhat familiar, it may be that I will include matter as to which I would like some information personally but which I do not think would be important to be included in the record.

If I may go through this rapidly with the understanding that Dr. Scheele or any of his associates may refer matters that are not pertinent to this hearing to our staff, I would appreciate it.

The CHAIRMAN. Very well.

Mr. HESELTON. First, I noticed that the bill, H. R. 8704, contains the date of June 30, 1957.

This morning, in reading your formal statement I marked the paragraph which I think was on page 29:

Supply: One of the most acute problems in the program today has been the difficulty of forecasting future production and release of the vaccine. The large number of tests required to insure safety of the vaccine, and the many scientific variables involved in the production and testing process, have made it impossible to estimate accurately the future production and release of vaccine. It is anticipated that early in 1956 the production and release of vaccine will become more stable and future production will become more predictable.

That raised in my mind the reason for using June 30, 1957, as against February 15, 1957, or some other date, having in mind the reasons why at least the conference committee adopted that earlier date in order to have more assurance of an earlier look at the program this year.

Can you tell us first why that date was chosen and, second, what there is in the record to date which gives you any assurance that you will be able to complete the program by that time and not sooner?

Dr. SCHEELE. Mr. Heselton, there is a certain amount of estimation which comes into the selection of that particular date and there are a certain number of factors which we took into consideration.

Looking at crude estimates of potential supply, it would seem that that date would get us beyond the point where the full intent of the act insofar as Federal help to the States by approximately $60 million of vaccine at present prices could be completed.

There is another thing. We do have the problem of third injections for children, although at whatever point we will have it, we will never be finished with this unless we go on forever, which we do not propose to do.

There is also proposed the giving of funds. You will recall the act advised that we can set aside, the States can set aside, 20 percent of the funds made available for them for execution of the program. So we have that continuing on even beyond the point where they might be buying vaccine.

The polio season begins to build up late in May, June, July. Our most intensive vaccination will come then through the spring period and on into the early summer. There will be a tendency to slow down the injections in the summertime.

So it would seem that June 1957 would be a conservative estimate of a time when we would come close to achieving the objective that the Congress had in mind when it passed the original act. It is conceivable that it might be a little earlier. It is conceivable that it might even take a little longer than that to finish off the program. But it seemed to us to be an average of these things, and it seemed to work out about that way.

Mr. HESELTON. You have approximately 65 million people within the priority age groups and among pregnant women, as far as you can estimate.

As I understand your testimony, they would require some 195 million cubic centimeters of vaccine?

Dr. SCHEELE. Yes, sir.

Mr. HESELTON. When do you anticipate the companies manufacturing this vaccine will have reached the point where 195 million cubic centimeters will be available?

Dr. SCHEELE. We are hopeful that by or before that June 30 cutoff time in 1957, it will be available. It is very difficult to project ahead and come out with any degree of accuracy. We discovered that in the past.

One is the difficulty of making the vaccine. One of the plants was at a strike recently, which slowed their production.

Mr. HESELTON. There are, as I understand it, six companies equipped to produce the vaccine?

Dr. SCHEELE. That is correct.

Mr. HESELTON. Have they furnished any estimate of their production up to June 30, 1957?

Dr. SCHEELE. Yes, sir.

We have gotten a crude estimate of production from 4 on their production in the next 6 months and in the 6 months beyond that, although they all point out the fact that there is probably more validity to their plans for the next 6 months than there may be in the following 6 months. We will have some idea regarding their potentials.

Another company—well, two other companies—has not submitted lots for approval and another is in process of getting approvals and getting back in production of vaccine for use. They at the moment do not care to make an estimate until they have actually had some experience in getting lots approved.

So we have some things which are actual company estimates and some things which are just our guesses, shall we say, of what would seem to be the potential based on our past experience.

Mr. HESELTON. Mr. Chairman, has this report been filed for the record?

The CHAIRMAN. That document has not been filed.

Mr. HESELTON. At page 2 of this report, you list 6 companies as filing license applications but, subsequently, on page 3 you indicate that, as I understand it, 4 have been—you use the word—"recleared" and one has not yet presented any vaccine for release.

Is that the situation as of this time?

Dr. SCHEELE. Yes, sir.

Eli Lilly; Parke, Davis; Pitman-Moore; and Sharp & Dohme; and Wyeth Laboratories and Cutter Laboratories were the firms licensed; that is six. Cutter has no lots of vaccine before us for clearance. Sharp and Dohme has no lots of vaccine before us for clearance. We have lots from the other four at the moment.

Mr. HESELTON. Are they producing for other countries, too?

Dr. SCHEELE. No, sir; they are not. The vaccine is under Department of Commerce export license.

Mr. HESELTON. Mr. Chairman, I am a bit disturbed about carrying the matter through to June 30 of the next calendar year in view of the fact that there is obviously the changing of Congress and that sort of thing, and I would want to examine much more closely the basis on which the date was arrived at.

Could you see that the staff furnishes us the material on which you base your estimates?

Dr. SCHEELE. We will be happy to.

(The information requested is as follows:)

ESTIMATES OF POLIO VACCINE PRODUCTION

(January 1–December 31, 1956)

Based primarily on estimates received from vaccine manufacturers, we anticipate that approximately 70 million net cc. of vaccine may be released between January 1 and June 30, 1956, and that the productive capacity of vaccine manufacturers could permit the release of approximately 16 million net cc. of vaccine per month after that time. Thus it is possible that during calendar year 1956 approximately 166 million net cc. of vaccine will be available for use. This amount plus the approximately 30 million cc. of vaccine released prior to January 1, 1956, would make a total of 196 million cc. available by December 31, 1956. These, of course, are rough estimates because vaccine production over this length of time will be influenced by many factors, such as demand and change in strain, if such change should be made.

This amount is approximately the quantity required for 3 injections for each of the approximately 65 million children under age 20 and expectant mothers. This requirement is based on 100-percent demand. It is unlikely, based on past experience, that demand will reach that high. Because of the recommended 7-month interval between second and third injections, however, all of these eligible persons would not be able to receive the full 3 injections by December 31, 1956. Extension of the expiration date of the act for an additional 6 months to June 30, 1957, would provide the time necessary for third injections if these production estimates are realized.

Dr. SCHEELE. May I say one additional thing?

Mr. HESELTON. Certainly.

Dr. SCHEELE. From the standpoint of the States and communities who have to plan ahead in the use of the vaccine, there is some advantage in giving them a fair amount of forward time, leeway, to get their programs into gear.

Mr. HESELTON. I appreciate that but did I not understand you to say that the bulk of the vaccination occurs prior to the period when polio was experienced and, in other words, it would occur during the spring months?

Dr. SCHEELE. Yes, sir.

Mr. HESELTON. That has been the record; has it not?

Dr. SCHEELE. Yes, sir; and then in the fall.

Mr. HESELTON. So what you are anticipating here are 2 major periods of vaccination rather than 1?

Dr. SCHEELE. Yes, sir; plus the fact, however, that we always have that 7-month gap between the second and third doses. If they have their second dose in June, they are going to run into December and January to get the last dose.

I think it should be made clear for the record, too, that in selecting the June 30 cutoff time, 1957, we had no intention of proposing a continuation of the program on a larger scale than was contemplated in the act that is now passed.

Mr. HESELTON. I appreciate that.

Dr. SCHEELE. We did not intend to go beyond that period.

Mr. HESELTON. I was attempting to obtain the basis on which you set the date.

The second question of some importance, it seems to me, is the question of priorities.

During the noon hour I received the January 19 issue of the New England Journal of Medicine, in which there is a report entitled "Evaluation of Poliomyelitis Vaccination in Massachusetts," by Dr. Pope and five of his associates.

Have you seen this?

Dr. SCHEELE. You mean the journal? I have seen a mimeographed copy of the report.

Mr. HESELTON. Yes.

I noticed one point that seems to confirm an impression I had. That is, taking the 3,608 of the 3,819 cases reported in Massachusetts from July 1 through November 30, that had been classified, there were 1,123 from zero to 4 years, 936 from 5 through 9, 402 from 10 through 14, and 233 from 15 through 19.

There were from 226 from 20 through 24, and then, significantly enough, it goes up again in the 25- through 29-age group to 307 and then begins to drop back, although in the 30- through 34-age group there were 214. So there were 747 cases in the 15-year-age group from 20 through 35, and 637 cases in the 9-year-age group from 10 through 20.

Some of the most harrowing cases have been cases among people above the age of 19, young mothers and young fathers.

Have you had sufficient experience to be able to say to us that our selection of this priority group is adequate? Should we examine the question even at the expense possibly of not accomplishing the full objective we had in mind in the present law? Should the priorities be broadened in view of this apparent incidence among older people who probably should receive substantial protection?

Dr. SCHEELE. We are caught on the horns of a dilemma.

There is risk at all these age levels in the United States and our supply of vaccine is short. So, in the selection of fairly broad spread, zero to 15, with the suggestion that not more than 10 years within that range be used, plus pregnant women, we have a situation in which the greatest amount of saving can come.

That saving, of course, is not worth anything if one happens to be 21 or 31 and he gets paralytic polio or bulbar polio and dies. So it is purely a matter of taking the supply as it exists and attempting to get it to those at the greatest risk, which means somebody has to give up.

If someone got it and was, say, 25 or 30, his risk is only one-fourth of that, say, of somebody in the 5- to 9-year-old-age group in Massachusetts, he is not going to get added to a lot of other people in the same age group, they are not going to get the relative protection as far as risk goes that these younger children would. It is expediency purely to get the greatest protection from the disease in those at greatest risk that we have any priorities at all.

We hope, too, as the supply increases, of course, we hope to get to the point where there is no priority exercised at all; in other words, so that all those who want it can get it.

Mr. HESELTON. I realize that that would be your objective.

However, I do suggest that possibly the emphasis on just extension of the time may overlook another factor which should be given consideration.

For instance, in this particular table, after you are by the 10- to 14-age group in the paralytic cases, the breakdown, male and female, is 86 and 61. Then 59 and 49, 40 and 47, and then 25 and 29, so that the 25- to 29-year group is relatively affected in the same degree as the 10- to 14-year group.

I recognize the practical difficulties confronting you or anybody else who has to make a decision or a recommendation, but it occurs to me that this committee may want to, certainly I want to, have somebody study this a little more carefully to see whether we are going in the right way or whether we may be taking—I do not mean that you are but that we may be taking—the easy course, which is just to extend the date without giving consideration to other factors of possibly equal importance.

I would appreciate it if you would see that somebody takes this, simply because it happens to be an objective study, and perhaps communicate with the chairman again as to that particular point.

Dr. SCHEELE. Yes, sir.

Mr. HESELTON. I do want to say, Mr. Chairman, that I was delighted to see in this report 1 or 2 sentences I would like to put in the record.

The CHAIRMAN. The gentleman may do so, but may the Chair state that it is the intention of the chairman to include this entire report in the hearing.

Mr. HESELTON. This New England report?

The CHAIRMAN. I am sorry, I am referring to the report of the Department.

Mr. HESELTON. There is one which I marked in particular.

Statements have been made that the poliomyelitis epidemic in Massachusetts this year was set off by live virus in the Salk vaccine, but to date no convincing evidence has been brought forward to substantiate this claim.

I think that is particularly important to us in terms of the suggestions that have been made that Massachusetts was a little slow and that there has been some criticism that it did not join with other States because of its concern as to how much of this live virus controversy might be valid.

Then, Mr. Chairman, in the last part of the summary:

The effectiveness of the vaccine for all cases of poliomyelitis was 53 percent. For paralytic cases, only, the effectiveness was 60 percent.

As a layman, this seems to me to be a very favorable comment in terms of what has been determined there at any rate as to the effectiveness of this particular vaccine at this stage.

Do you agree, Doctor?

Dr. SCHEELE. Yes, sir; we certainly do.

Mr. HESELTON. There may be other things in the report, Mr. Chairman, I would like to have the staff go over and submit to you.

Dr. SCHEELE. Mr. Heselton, may I make a comment on your earlier comment about the priority groups?

In arriving at these suggested priority groups, we are doing it for the United States as a whole, and we have an advisory committee actually with a variety of representatives on it and which you know about. They are listed in this document we gave you. They are looking at the country as a whole, looking at the individual States, too, of course, and then coming up with, in a sense, an average to recommend.

However, as was pointed out this morning when we were asked if we had exercised our powers conferred by one of the sections of the act to set rigid age priorities as part of our demand within the plan submitted by the State, I commented that we had not done that. The only restriction on the State is a little later in the act, where it says it

should be for people from zero up to those who had not passed their 20th birthday, and expectant mothers.

Then the next echelon of decision making is at State level. We have a guide which we have arrived at and put out to the States. Each State has a polio vaccine advisory committee consisting of doctors, epidemiologists and others, and they can fit it to adjust to their own needs.

Actually, a few States have adjusted the vaccine in the free program up as high as the 20th birthday. Not very many have, but a few did, because they felt that in their particular cases there were enough problems in the upper age brackets.

So there is a flexibility which is up to them to exercise.

In the case of Massachusetts, their committee can advise, in spite of our suggestion for the country as a whole, what will best fit their needs.

The CHAIRMAN. They may best fit their priority up to 20, any years within that span?

Dr. SCHEELE. That is right.

Mr. HESELTON. I have here a printed letter which was sent out to all the physicians subsequent to the decision of the Massachusetts Advisory Committee on Polio. That decision was made in a meeting on January 9. I take it you may have seen the letter but I want to refer to 2 or 3 particular portions of it.

After referring to the fact that the committee believes the protection to be expected is now greater than a potential risk to the vaccinated individual and to those with whom he comes in contact, the committee states it also believes that total freedom from live virus cannot be assured in this vaccine and that the vaccine may possibly on rare instances induce the disease in those vaccinated or in their contacts.

Is that a fair statement?

Dr. SCHEELE. I think in a gross way, it is fair. We have never said that the vaccine could be produced with absolutely no particle of virus remaining. I do not believe we would go along with that part which would say that the amount that could come through the safety tests would be enough to cause infection.

Here I suppose we may not be on the soundest grounds because probably we do not know too much about the individual reactions. Enough has been done to satisfy most of those who know the polio virus field. We do know that in use of the millions of cubic centimeters which has been retested and made with the new standards, we have not had problems emerge. So we feel pretty sure.

I think the group there in their statement is leaving a proper physician's safeguard. None of us want to make statements about perfection and that sort of thing when, in fact, there is always one little bit of knowledge that one does not have in a given moment.

Mr. HESELTON. I appreciate the difficulty, Doctor, and perhaps I should not have asked you to comment on 1 or 2 sentences taken from a letter. That is why I hesitated this morning to ask the questions.

I think, in fairness to you and the men who served on this committee and Dr. Kirkwood, I should read into the record, after what you have said, these 3 or 4 sentences.

Moreover, what effect such recent improvements toward the safety of the vaccine has on the efficacy of the material as a preventive of the disease is yet to be determined. Indeed, the vaccine is very definitely in the developmental stage and needs much more scientific study. One cannot expect perfection at

this early date. For this reason the committee has been confronted with great difficulties. Vaccines in the prevention of other diseases have undergone radical improvements over a period of years, and the same is to be expected in the field of poliomyelitis.

I am just reading that in the record because I think you feel, as I do, that they made an effort to be objective and fair in their appraisal.

There was another sentence, however, I wanted to ask you about because of a reference in your formal statement.

You said:

A large scale effort is being made to discover a suitable strain of type I virus as a substitute for the Mahoney strain.

They have this to say in their letter to the physicians, that, furthermore, the committee recognizes that research still continues for a suitable strain of type I virus, and I presume they are referring to some substitute.

Dr. SCHEELE. That is correct.

Mr. HESELTON. How far have you progressed?

Dr. SCHEELE. Dr. Shannon?

Dr. SHANNON. At the present time there are three strains that are somewhat more desirable, have more desirable characteristics, from the standpoint of virulence. They are now undergoing tests as to their ability to grow in culture and their ability to inactivate in systematic fashion with formalin.

I would say at the present time we are right in midstream. I do not think we could put a timetable on the rate of development, I do not think we could be absolutely certain that within any reasonable time—that is, within 5 or 6 months—most certainly will we have a new strain.

I will say, though, that all the time that can be devoted to this by the pharmaceutical houses, by a number of university groups, is being devoted to this particular problem.

Mr. HESELTON. They go on to say that this committee arrived at that decision on the assurance that the Federal Government would comply with the new methods of production, and so forth. I am not going to try to find it here, but I have the recollection that there was some suggestion that you had arrived at your revised regulations as to production and possibly safety tests some time last spring, but I catch in here the date of November 1955.

I would like the record to be clear as to when your last revised regulation went into effect and whether you anticipate other revisions in the near future or in the future.

Dr. SHANNON. Most certainly there will be revisions in the future but we do not anticipate any substantative change in the near future. The work that is going on now relates to the improvement of potency testing, relates to a clearer definition of some of the factors which relate to ability to reproduce in a systematic way a manufacturing procedure, and they are not directed to a modification of the basic manufacturing process itself. But, as with all these vaccines, there will be modifications as time goes on.

In some of these, they will be introduced by one member of the pharmaceutical industry, at other times all members will take them up. But this, I would say, is a normal evolution of a vaccine, sir.

Mr. HESELTON. If I understand you correctly, you are working trying to develop some type of medium, if medium is the right term, some alternative to the Mahoney strain. Everyone concerned is working to-

ward that end and that might happen, let's say, next month or within 6 months?

Dr. SHANNON. No, sir. The timetable is such that it could not happen within a 6-month period.

Mr. HESELTON. Could it happen within 8 months?

Dr. SHANNON. Yes, sir; it could.

Mr. HESELTON. If it does happen, that will involve, will it not, some change in the production and some change in the production schedule?

Dr. SHANNON. We would hope that we would know far enough in advance when the changeover was going to take place that it could be done without seriously modifying the production schedule. What one would do during the changeover period is to produce and activate types II and III during the period of time you were changing over from type I, and then feeding into the production cycle all the facilities on the type I to make up for the lost time.

Mr. HESELTON. I am speaking as a layman. From what I have gathered during the hearings we have held and from what I have read, I would assume that something might occur that would outdate, if I can use that word, the vaccine that was in the hands of the authorities who are empowered to administer it; that is, you might accumulate quite a quantity of what now seems to be the best vaccine you have available, but, through some new discovery, and I will use the 8-month period, through some new discovery in 8 months, you might feel in your own sound judgment and the medical world would agree with you that in the best interests of everyone concerned, every bit of vaccine that had been sent out should be withheld and this new type should be substituted.

That may be an extreme idea but it is one that is in my mind and one I would like to have you discuss.

Dr. SCHEELE. May I comment on that? We would hope that the changeover in the availability, beginning availability, of a vaccine without Mahoney would not make obsolete, would not make unusable in the minds of any people, any remaining supply with Mahoney. The very fact that Massachusetts, that the committee recommended that they go forward with their mass program with this vaccine with Mahoney, they now feel that the vaccine can be made safely if it follows the latest standards is evidence of its acceptability. That decision should not be made if there is any question about the Mahoney strain.

We should not have been recommending this vaccine all of these many months. This is a little like automobiles. There are 1955 models and 1956 models. The 1955 models are good, they will take us where we want to go. Maybe there are a few new gadgets in the 1956 models and some will want to buy them, but that does not mean that what has been made in the 1955 model is not good.

It could be that there could be something in using a new strain that would not work out well. So many of our epidemics in the United States have had a high prevalence of strain I. I believe the Massachusetts epidemic was largley a strain I epidemic.

We know, for example, that one of the countries experimenting with a new strain I found that, when given to one of its test groups, got very little antibody response as they did with strains II and III. This is the reason there are these problems of changeover. It is a goal and we want to be sure, though, that we have not sacrificed the protective value against strain I in the changeover. So we would hope that there would

still be plenty of people who would want to have any vaccine that would be outstanding with Mahoney in it to use it because it is a part of the total supply.

In my opinion, it would be a great tragedy if a child somewhere did not get the present type vaccine while somebody waited, or while somebody let some of that go down the drain later, and then there was not enough of the other one to pick up and carry on and, as a result, that child became paralyzed or died. To me, from the medical standpoint, it would be quite inexcusable.

So we hope to see the smooth changeover and we hope to see continued utilization of whatever remains of the Mahoney strain vaccine into the new one, if, in fact, we ever arrive at the point where we can change over.

Mr. HESELTON. That is much clearer to me and very helpful to my own thinking.

I shall read this other paragraph because I think it serves to point up what has been in my mind while this matter was discussed this morning as to the nature of the problem before this committee, and as to whether we are fully discharging our responsibility by simply either approving a designated date or setting another date or should we say there is something more, something as important we have to consider and we need some evidence on it.

This is the paragraph to which I have reference:

> In making this recommendation, the committee is aware that the present vaccine has not as yet undergone full field experience to determine the degree of its effectiveness although it has passed required laboratory potency tests. Furthermore, at the present time the ultimate duration of protection inferred by any polio vaccine is not known.

The bulk of this I assume you agree with?

Dr. SCHEELE. Yes.

Mr. HESELTON. So you have a problem where we can anticipate and hope that through the efforts that are going on now and will be made, improvements are possible. It might be that you would want to come back to the committee with some type of recommendation in terms of the priorities or in terms of some feature that is in the basic law that we are not dealing with in this particular bill.

Is that a fair statement to make?

Dr. SCHEELE. Yes, sir; I think that is a very fair statement, and I have assumed that we would come with that, even though it were something before the termination date is set.

Mr. HESELTON. I have not the slightest doubt. Perhaps I should not have put it in the form of a question.

Finally there were a few points I checked as to which I would like your comments. This membership of the committee listed on pages 16 and 17, is that current?

Dr. SCHEELE. I believe it is, sir. Yes, sir; that is current.

Mr. HESELTON. Lodged in my mind is the thought that the American Medical Association or some group held a meeting, I believe in Boston this fall, at which they made certain recommendations as to this particular program. I do not recall what they were except that I think there was some suggestion of abandoning the position we took as to the needs test.

Has that been discussed in your prepared statement or in anything you furnished to the committee?

Dr. SCHEELE. No, sir; it has not. Our assumption, or, rather, our recommendation in this instance, was that the present act merely be extended datewise. We had not recommended any change in any of the other language.

Mr. HESELTON. You prefer to comment on that if the question is raised, rather than right now?

Dr. SCHEELE. We think that the bill as passed earlier in relation to the means test is all right. That is arguable of course. I believe it causes some problems in Massachusetts at the present time, but we also understand those are surmoutnable problems.

Mr. HESELTON. I noticed, with reference to the Governor's advisory committee, which, as I recall, was set up during or immediately following the meeting that was held at the Department last year, the statement is made:

> General approval was indicated by the committee, which agreed to poll all governors with respect to certain questions.

I did not find anywhere what the questions were or what the answers were. Did you receive something that ought to be presented to the committee?

Dr. SCHEELE. Those questions were questions of whether they felt that they could have a successful program in reaching the people of greatest risk, in avoiding what was then called black markets, gouging, and things of that sort, on a voluntary basis; whether or not they, as governors, would be willing to work with their health officers and set up advisory committees and to play a role as governors in attempting to persuade people to live within the voluntary agreed program in order that we might avoid the necessity which some people felt——

Mr. HESELTON. I take it the answers to the polls were that the program could be initiated? It was initiated and you are satisfied?

Dr. SCHEELE. Yes, sir; it was a very unanimous agreement by the governors that working with them, we could get along on a voluntary basis. I could also say that organizations like the American Medical Association, the State medical associations, sent telegrams to the secretary of our Department and indicated that they, too, were going to put their shoulder to the wheel to make the voluntary program operate.

I might say one more thing on the means test. I have a lot of faith in our American physicians, and while the bill or act is written as it is, I think the actual practice by the physicians the country over is such that it probably does not make much difference which way it is written. The doctors are going to try to stretch this supply so that those who are neediest get the free vaccine, while at the same time trying to use the program in a way that will get the most protection to the largest number of people.

Mr. HESELTON. This program, as you have administered it, has involved the voluntary cooperation of State and local authorities, physicians, hospitals, pharmacies, druggists, and the various health agencies which I have mentioned.

As I understand it from listening to some of the difficulties you listed, you never had any occasion where you felt there was any serious failure to cooperate on the part of any single person. Am I right about that?

Dr. SCHEELE. That is correct.

Mr. HESELTON. I think you are to be commended, and all others should be commended, for what I personally think is a magnificent

effort. It may not be recognized now, but as soon as the results are fully clear, I think the American people will join in my comment.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Heselton.

Without objection, the report of the Department of Health, Education, and Welfare on the progress of this program, dated January 24, 1956, will be included in the record.

(The report referred to follows:)

PUBLIC HEALTH SERVICE PROGRESS REPORT ON THE POLIOMYELITIS VACCINATION PROGRAM, JANUARY 24, 1956

Department of Health, Education, and Welfare, Public Health Service
Washington 25, D. C.

INTRODUCTION

The purpose of this report is to review the progress of the poliomyelitis vaccination program since April 12, 1955. Because events prior to July 25, 1955, have been discussed in detail in previous reports 1, 2, 3, they are only briefly summarized here. Primarily, this report deals with progress in the production, clearance, distribution, and use of poliomyelitis vaccinne, and special attention is given to the present status of the program.

The two major goals of the Department of Health, Education, and Welfare with respect to the poliomyelitis vaccine program have been: 1, to insure safety and effectiveness of the vaccine produced; and 2, to help obtain equitable distribution and use of the limited supply of vaccine available.

The report is keyed to these goals, and is presented in three main parts.

Part I reviews the steps that have played important roles in determining the safety and effectiveness of the vaccine.

Part II is devoted to activities which, moving forward simultaneously on another front, have had a significant effect on the supply, distribution, and use of poliomyelitis vaccine.

Part III summarizes the current status of the program from the standpoints of safety, effectiveness, supply, distribution, and use.

PART I. SAFETY AND EFFECTIVENESS

LICENSING OF PRODUCERS OF POLIOMYELITIS

As a direct result of the field trials with Salk vaccine carried out by the National Foundation for Infantile Paralysis, the Public Health Service Laboratory of Biologics Control[1] on April 12, 1955, issued official minimum requirements for poliomyelitis vaccine (4). Also, on advice of a group of special consultants, it accepted the evidence available as warranting licensing of six manufacturers of the vaccine. Consequently, on the same day, upon the Surgeon General's recommendation, the Secretary of Health, Education, and Welfare issued licenses to the following companies which were producing vaccine and had filed licenses applications: Parke, Davis & Co.; Eli Lilly Co.; Wyeth Laboratories, Inc.; Cutter Laboratories; Pitman-Moore Co.; and Sharp & Dohme.

Stocks of vaccine, tested by manufacturers in anticipation of licensing, were already on hand. Samples of the vaccine had been submitted to the National Institutes of Health, which had tested one or more lots of each manufacturer prior to licensing. After review by the Laboratory of Biologics Control of submitted records of manufacturing and testing (protocols), a number of lots of vaccine were released for use, thus enabling the national program of poliomyelitis vaccination to get underway within 2 days after the licenses were issued.

TESTING AND CLEARANCE OF THE VACCINE

Suspension and resumption of the vaccination program

On April 26 five cases of paralytic poliomyelitis were reported in vacinees who had been injected with vaccine produced by the Cutter Laboratories. The following day, this company was requested to withdraw its product, and there-

[1] Now the Division of Biologics Standards, which was established on June 9, 1955. (See p. 5 for fuller explanation.)

upon notified its distributors to recover all vaccine. Experts from the National Institutes of Health were sent to Cutter Laboratories to examine the records and the physical plant, and efforts were begun to test Cutter products by enlisting the aid of 16 cooperating laboratories.

In addition, upon recognition that cases of poliomyelitis were occurring in association with vaccine manufactured by the Cutter Laboratories, the Surgeon General immediately (April 28) established the national poliomyelitis surveillance program. The purpose of the program was to provide a clearinghouse for the collection, consolidation, and dissemination of all pertinent epidemiologic information regarding the occurrence of poliomyelitis in vaccinated and unvaccinated persons. Operation of this program is discussed later in this report.

By April 30, 17 cases of paralytic poliomyelitis had been reported among children injected with Cutter vaccine. Upon recommendation of a Special Committee of Experts, the Surgeon General on May 8 recommended suspension of vaccination programs until each manufacturing plant had been visited and its records and procedures inspected. As a result of visits to the Parke Davis and the Eli Lilly plants, vaccine produced by these two companies was recleared for use. Wyeth and Pitman-Moore vaccine was subsequently recleared also. The Sharp & Dohme Co. has not yet presented any vaccine for release.

The Cutter report.—A prolonged and intensive study was made of the Cutter manufacturing plant, its protocols and records, and the completed product in an effort to determine the cause of the Cutter problem. The report of the study was issued by the Surgeon General on August 25, 1955 (5).

Reappraisal of production procedures and testing methods

By May 15, a total of 54 cases of paralytic poliomyelitis associated with Cutter vaccine had been reported. The Public Health Service decided that advice from the most experienced workers in the poliomyelitis field, based on a continuing review of production procedures and testing methods, was needed.

The Technical Committee on Poliomyelitis Vaccine.—The Technical Committee on Poliomyelitis Vaccine (3) was appointed by the Surgeon General on May 23, 1955. This committee has performed the following functions: 1, reviewing production and testing data on lots of vaccine submitted by manufacturers; 2, advising on the release of such vaccine; 3, studying the details of manufacturing and testing procedure; 4, recommending requirements for production and testing which assure uniformly safe and potent vaccine; and 5, developing a collaborative research program which would continue to insure a sound basis of safe and effective manufacture of the vaccine.

Through repeated meetings and close cooperation among the manufacturers, the Technical Committee on Poliomyelitis Vaccine, and the public Health Service staff of scientists, it has been possible to identify and develop corrective measures for a number of technical problems affecting consistent production of safe vaccine. These problems are discussed in the committee's interim report (6), which includes the following statements:

"In summary, the Committee is of the opinion that the principal factors which were involved in manufacturing difficulties have been identified and corrective measures have been taken.

"Among these factors is the absolute need for removal of particles within which virus may be protected from inactivation by formaldehyde. Provisions have been made to insure as far as possible the removal of such protected particles by suitably spaced filtration procedures.

"In addition, the safety test program has been strengthened by improved sampling procedures in the tissue culture tests and by increasing the sensitivity of the monkey safety tests. These measures, together with continuous review of plant production records, assure the safety of released vaccine and should make possible an increased availability of vaccine."

Throughout this period of intensive study, research leading to improvements and refinements in the vaccine has been emphasized. As the investigations proceeded and new information became available, the Public Health Service minimum requirements, governing poliomyelitis vaccine, have been amended accordingly. The principal changes involve improved filtration and more sensitive monkey tests.

Amendments to the minimum requirements.—Since the minimum requirements were first issued on April 12, 1955, they have been amended several times. Briefly, the subject of each may be stated as follows:

The first amendment to the minimum requirements, which was issued on April 19 (7), was concerned with a technical interpretation of the potency re-

quirements. The second amendment, issued on May 26 (8), imposed more rigid methods of safety testing.

The adoption of these amendments and their application to the product enabled the vaccination program to continue. However, these changes in testing procedures served to retard temporarily the flow of vaccine. The tests now required larger volumes of material, thus tying up much of the personnel and resources which had previously been employed in the production of vaccine.

Continued investigation by the Technical Committee for Poliomyelitis Vaccine, the Division of Biologics Standards, various cooperating laboratories, and industry, led to the issue of amendments 3 and 4 to the minimum requirements.

Amendment 3 (9) is concerned with a new monkey test evolved through the cooperation of various laboratories with the Division of Biologics Standards.

Amendment 4 (10) is concerned with the filtration steps designed to remove particulate materials from single strain pools prior to and during the process of inactivation and with the use of supplementary inactivation processes.

Amendment 4 also introduced modification of the monkey test, which emerged from experience since its introduction on September 10.

Establishment of the Division of Biologics Standards

Programs within the Division.—The Division of Biologics Standards was established on June 9, 1955, as a component part of the National Institutes of Health to further expand and strengthen the Service's resources for controlling the safety of biologics products. Functions previously performed by the Laboratory of Biologics Control are included among the responsibilities of this new Division.

One of its first duties was to detail technical representatives to serve as liaison between the Public Health Service and each manufacturing concern. The resulting continuous interchange of information between industry and the controlling agency has been most helpful. Continuous surveillance of each manufacturing process insures knowledge of inconsistency of performance should it occur. Heretofore, this had not been possible. A practical testing program has been instituted which is served by five tissue culture teams and is capable of testing all samples of vaccine submitted. In addition, a unit capable of performing monkey safety tests on a great proportion of vaccine samples submitted is in operation.

Cooperative programs.—Much of the research being carried out at the present time is based on the combined efforts of the Technical Committee for Poliomyelitis Vaccine, the manufacturing industry, and the Division of Biologics standards. Problems under study include: methods of purifying vaccines, comparison of methods and techniques of tissue culture safety tests, the study of improved methods of employing monkey safety tests, and simian (wild) viruses and their relation to vaccine production and testing. Considerable effort has been expended in an attempt to improve the manufacturing methods employed in the various firms. A large-scale effort is being made to discover a suitable strain of type I virus as a substitute for the Mahoney strain. This is a most complex problem, with many diverse aspects such as inactivation, pathogenicity, potency, and many related problems. The interim report of the Technical Committee on Poliomyelitis Vaccine (appendix F) summarizes the present status of this problem from a technical viewpoint.

Other activities concerned with poliomyelitis vaccine.—The National Institutes of Health, in conjunction with the Technical Committee and representatives of the Surgeons General of the Army and Navy, have drafted the minimum requirements for the manufacture of poliomyelitis vaccine into regulations governing manufacture of this product. In addition, the National Institute of Health have been concerned with a review of the Biologics Control Act of 1902 with a view toward strengthening and modernizing control of the safety, purity, and potency of biologic products.

Surveillance of the disease and field evaluation of the safety and effectiveness of the poliomyelitis vaccine

The national poliomyelitis surveillance program, with headquarters at the Public Health Service Communicable Disease Center in Atlanta, Ga., has proceeded concurrently with activities already described. This program, by following epidemiologically the experience of vaccinated and nonvaccinated children, has provided a double check on the success of corrective procedures developed by the virologists. In addition, it has demonstrated the effectiveness of the vaccine (11).

Epidemiologic observations on vaccine safety

Poliomyelitis in Cutter vaccinated children and their contacts.—The first concern of the Poliomyelitis Surveillance Unit was to evaluate the significance of the cases of poliomyelitis which were occurring among Cutter vaccinated children and their contacts. Upon study, certain characteristics became evident: (1) A concentration in certain geographic areas; (2) the association with particular lots of vaccine; (3) the grouping of the onset of most of the cases with appropriate incubation periods following inoculation; and (4) the correlation between the site of inoculation and the site of first paralysis in a majority of the vaccinated cases. Because of these characteristics, it was concluded that the development of the disease in some of these patients was the result of the presence, in infective amounts, of live poliomyelitis virus in some distribution lots of Cutter vaccine. Laboratory studies have since supported this conclusion.

Experience with lots of vaccine since revision of testing standards.—Since the revision of safety standards in May 1955, there has been no epidemiologic evidence that any lot of vaccine of any manufacturer has been unsafe. Since May 13, all lots of vaccine have been released under revised safety standards. Epidemiologic surveillance for possible untoward incidents has been constantly maintained. All States and Territories report on a weekly basis cases of poliomyelitis which occur among vaccinated children. These are tabulated by lot number so that individual cases associated with the same lot but occurring in different States will be promptly recognized. Special attention is directed toward cases which occur at an interval of 4 to 14 days after inoculation and to paralytic cases showing first paralysis at the site of inoculation. The essential data on each vaccinated case are made available to health authorities.

The cases of poliomyelitis that have been reported among vaccinated persons since the first of July have shown certain distinctive characteristics. Over three-fourths have been reported as nonparalytic. Most have occurred more than 30 days after vaccination. Those few occurring in the interval 4 to 14 days did not exceed the normal expectancy of coincidence. Among the relatively infrequent paralytic cases, instances with first paralysis occurring within this interval at the site of inoculation have been conspicuously rare. Thus, from an epidemiologic viewpoint, there is no evidence that use of vaccine has caused poliomyelitis since the adoption of the new safety standards.

Measurement of the effectiveness of vaccine

Special studies.—Preliminary reports indicate encouraging results regarding the effectiveness of the poliomyelitis vaccine, as demonstrated by experience from at least one injection. The restriction of inoculations to first- and second-grade schoolchildren during the spring and summer of 1955 provided a unique opportunity for special studies to evaluate effectiveness. Approximately 20 States are conducting such investigations. Preliminary reports have been received from 11 States and 1 city for inclusion in the 2 tables below. The size of the study population and the number of cases by paralytic status are shown for each area in table 1. These data are used to calculate attack rates as shown in table 2.

TABLE 1.—*Summary of special studies reported from 12 areas*

[Preliminary reports received through Nov. 1, 1955]

Area	Age group studied	Period studied		Vaccinated			Unvaccinated		
		From—	To—	Population	Paralytic	Nonparalytic	Population	Paralytic	Nonparalytic
California	6-8	June 15	Oct. 15	395,000	13	47	431,000	43	45
Connecticut	5-9	Jan. 1	Oct. 22	106,120	6	38	89,400	18	59
Florida	5-9	Apr. 15	Oct. 21	149,664	2	23	224,507	11	25
Georgia	6-11	Apr. 16	Oct. 23	174,200	6	6	262,400	20	19
Illinois	6-9	Apr. 18	Sept. 15	357,000	5	45	326,000	34	80
Maryland	5-9	Apr. 12	Oct. 8	112,000	4	.....	158,000	27	.....
Minnesota	6-9	May 20	Oct. 28	112,115	3	21	33,259	10	12
New York City	6-7	June 1	Oct. 21	166,000	9	13	87,000	19	32
New York	6-10	May 21	Oct. 21	448,569	18	128	282,000	59	111
North Carolina	5-9	Apr. 12	Oct. 21	196,466	4	19	232,133	26	58
Oregon	7-9	May 22	Aug. 23	47,812	1	2	46,188	7	4
Washington	5-9	May 15	Oct. 14	69,123	4	1	190,179	40	20
Total	.....	.....	.....	2,334,109	75	343	2,362,066	313	465

TABLE 2.—*Summary of special studies reported from 12 areas—Attack rates by paralytic status among vaccinated and unvaccinated children*

[Preliminary reports received through Nov. 1, 1955]

Area	Paralytic rate per 100,000		Nonparalytic rate per 100,000	
	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated
California	3.3	10.0	11.9	10.4
Connecticut	5.7	20.1	35.8	66.0
Florida	1.3	4.9	15.4	11.1
Georgia	3.4	7.6	3.4	7.2
Illinois	1.4	10.4	12.6	24.5
Maryland	3.6	17.1		
Minnesota	2.7	30.1	18.7	36.1
New York City	5.4	21.8	7.8	36.8
New York	4.0	20.9	28.5	39.4
North Carolina	2.0	10.8	9.7	25.0
Oregon	2.1	15.2	4.2	8.7
Washington	5.8	21.0	1.4	10.5
Total	3.2	13.2	14.7	19.7

As shown in the second table, there is a marked difference between the attack rates for the vaccinated and unvaccinated groups. For paralytic cases, the rates are from 2 to more than 5 times greater in the unvaccinated than in the vaccinated groups. The total paralytic rate for the 12 areas combined was 4 times greater in the unvaccinated than the vaccinated group. For the nonparalytic cases, no differences were observed in some States, and rates in others for the unvaccinated were two or more times greater.

When final data—giving more accurate classification of cases—are available, some changes in the precise rates may be anticipated. It seems doubtful, however, that there will be a major departure from the favorable trends already noted.

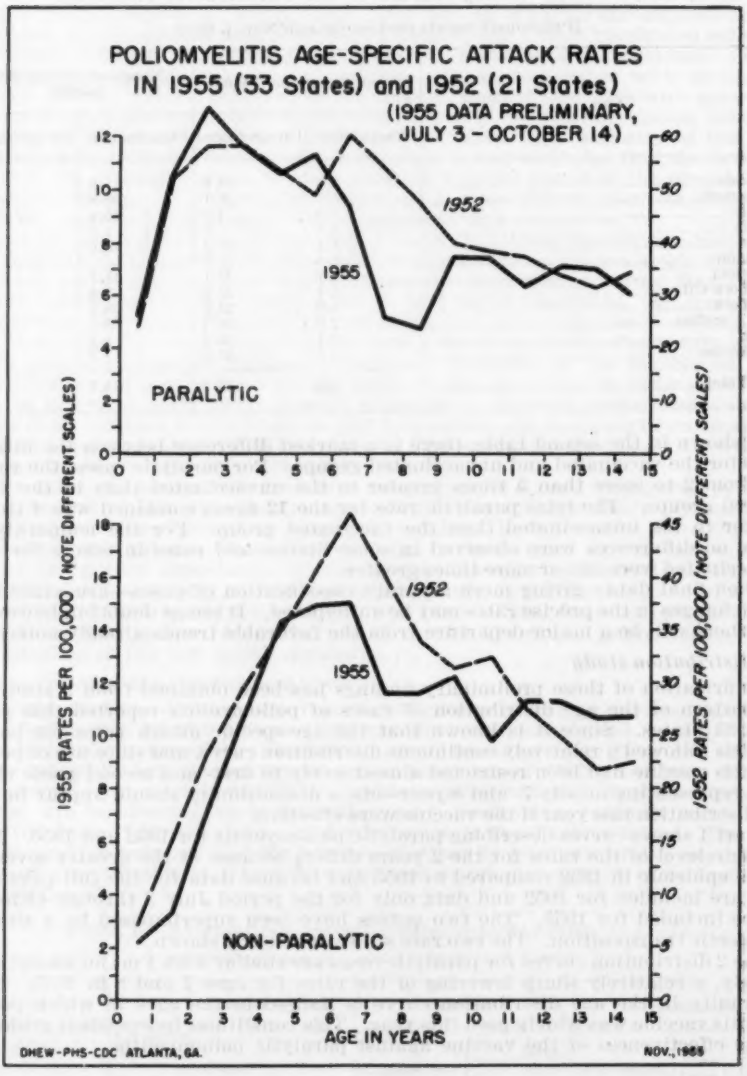
Age distribution study

Confirmation of these preliminary findings has been obtained from a study of the pattern of the age distribution of cases of poliomyelitis reported this year from 33 States. Since it is known that the age-specific attack rates for poliomyelitis followed a relatively continuous distribution curve, and since use of poliomyelitis vaccine had been restricted almost solely to first- and second-grade children representing mostly 7- and 8-year-olds, a discontinuity should appear in the age distribution this year if the vaccine were effective.

Chart 1 shows curves describing paralytic poliomyelitis for 1952 and 1955. The absolute level of the rates for the 2 years differs because of the greater severity of the epidemic in 1952 compared to 1955 and because data for the full calendar year are included for 1952 and data only for the period July 3 through October 14 are included for 1955. The two curves have been superimposed by a simple arithmetic transposition. The two rate scales are clearly shown.

The 2 distribution curves for paralytic cases are similar with 1 major exception; namely, a relatively sharp lowering of the rates for ages 7 and 8 in 1955. Discontinuity in the age distribution curve is limited to the ages in which poliomyelitis vaccine was widely used this year. This constitutes independent evidence of the effectiveness of the vaccine against paralytic poliomyelitis.

CHART 1



In the lower half of the attached figure are shown age distribution curves for nonparalytic cases in 1952 and 1955. The same type of transposition factor has been used to superimpose the curves. No sharp discontinuity is discerned that can be clearly attributed to an effect of the vaccine on nonparalytic cases.

This evidence pointing to effectiveness of the vaccine in the vaccinated age group is substantiated by data on hospital admissions reported to the National Foundation for Infantile Paralysis for 1954 and 1955.

Thus, the epidemiological field studies conducted by the Poliomyelitis Surveillance Unit of the Public Health Service, working cooperatively with State medical and public health organizations throughout the poliomyelitis season, support the laboratory findings that the vaccine is safe and effective.

PART II. SUPPLY, DISTRIBUTION, AND USE OF POLIOMYELITIS VACCINE

With announcement of the successful results of the 1954 field trials of Salk poliomyelitis vaccine, attention was immediately directed toward questions of supply, distribution, and use.

SUPPLY OF VACCINE LIMITED

Large-scale production of any new biologic product presents initial technical problems which can be solved only through experience. The problems inherent in the production of Salk vaccine are among the most complex in the field of large-scale biologic preparations. Hence, it was recognized that—even under the most favorable circumstances—demand for the vaccine would probably exceed the supply for a number of months.

On April 14, the President directed the Secretary of the Department of Health, Education, and Welfare to survey and report to him on the best means of assuring an equitable distribution of the Salk poliomyelitis vaccine. This report was submitted to the President on May 16, 1955 (1).[2] A followup report, supplemental to the original, was submitted on July 25, 1955.

DEVELOPMENT OF THE PLAN FOR EQUITABLE DISTRIBUTION OF VACCINE, TO TAKE EFFECT UPON COMPLETION OF NATIONAL FOUNDATION FOR INFANTILE PARALYSIS PROGRAM

Program of the National Foundation for Infantile Paralysis

In October 1954, the foundation negotiated contracts with vaccine manufacturers for enough material to inoculate 9 million children, provided the field trial indicated that the vaccine was effective. After consultation with a committee composed of representatives of the State and Territorial Health Officers Association, epidemiologists, and other health experts, it was decided to use this vaccine for first and second grade children. Subsequently, the foundation decide to limit its purchase of vaccine to 18 million cubic centimeters—enough for 2 injections for all first- and second-grade children, and for all participants in the field trials who had received placebo injections. In addition, children who had received vaccine in the 1954 field trials were to be given a booster injection. July 1, 1955, had been set as the goal for completion of this program.

The first objective of the Federal Government after success of the field trials was announced on April 12, 1955, was to help assure rapid completion of the National Foundation's program. Because of production and testing problems referred to earlier in this report, this schedule was greatly delayed. However, as vaccine has been released, needs for the foundation's program are being given priority until they are fully satisfied. From April 12 to late July, practically all vaccine released was shipped to the National Foundation for Infantile Paralysis to carry out its program. (During this period, only 563,000 cubic centimeters of vaccine were released for general sale; all prior to May 1.) Vaccine first became available for broader use on July 30. Since that time, the foundation's orders have continued to be filled prior to allocation of vaccine for other purposes. As of December 31, 1955, approximately 13½ million cubic centimeters of vaccine had been released to the National Foundation.

National Advisory Committee on Poliomyelitis Vaccine

As one of the first steps in considering the problem of distributing the vaccine on an equitable basis, a National Advisory Committee on Poliomyelitis Vaccine was appointed. The functions of the Committee were to make recommendations to the Department regarding: (1) the best means of assuring an equitable distribution of the vaccine; (2) the age groups which should be given priority to receive the vaccine because of their greater susceptibility to poliomyelitis; and (3) other broad problems which relate to the distribution and use of the vaccine.

The Committee is composed of representatives of the medical and pharmaceutical professions, the public health administration field, and the general public.

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[2] The many factors limiting the supply of vaccine available and the difficulties of estimating future production schedules were discussed in the May 16 report to the President (1). Moreover, during the early summer months, the problem was further complicated by the necessity for reappraisal of production and testing methods—referred to in part I of this report.

The present membership of the Committee and the organizations represented are as follows:

Chairman: Dr. Chester Scott Keefer, Massachusetts Memorial Hospital, Boston, Mass.

Executive secretary: Dr. Russell E. Teague, Chief, Poliomyelitis Vaccine Activity, Public Health Service

Members:

Dr. Daniel Bergsma, state commissioner of health, State Department of Health, Trenton 7, N. J.

Dr. George H. Uhl, health officer, city health department, Los Angeles, Calif.

Dr. Malcolm Phelps, American Academy of General Practice, El Reno, Okla.

Dr. Philip S. Barba, American Academy of Pediatrics, 5919 Green Street, Germantown, Pa.

Mrs. Rollin Brown, president, National Congress of Parents & Teachers Association, 700 North Rush Street, Chicago, Ill.

Mrs. Charles L. Williams, president, National Congress of Colored Parents & Teachers Association, 1200 Northwest Sixth Avenue, Miami, Fla.

Dr. Robert P. Fischelis, executive secretary, American Pharmaceutical Association, 2215 Constitution Avenue, Washington, D. C.

Mr. Frank W. Moudry, National Association of Retail Druggists, Fifth and St. Peter, St. Paul, Minn.

Dr. Julian P. Price, trustee of American Medical Association, 117 West Cheves Street, Florence, S. C.

The secretariat to the committee is made up of staff of the Public Health Service, which also serves as the administrative unit in connection with interstate distribution activities.

On May 2, 1955, the Committee held its first meeting. As the first order of business, the Committee endorsed the development and establishment of a voluntary system of vaccine distribution and recommended that children aged 5 through 9 be given the first priority to receive the vaccine. This Department concurred in these recommendations.

Interstate Plans for Distribution of Poliomyelitis Vaccine

Following the May 2 action of the National Advisory Committee on Poliomyelitis Vaccine, the Public Health Service continued in the development of a plan for the distribution and use of poliomyelitis vaccine.

Consultation with many groups and agencies.—In formulating plans, the Public Health Service consulted extensively with the vaccine manufacturers, representatives of the pharmaceutical and drug industries, the medical and public health professions, and the conference of State governors. Advice was sought also from organizations representing the consumer public.

Specifically, the following discussions were held, following two large preliminary meetings—the first with representatives of technical and scientific groups; the second with representatives of national organizations of the consumer public;

(*a*) Twice conferences were held with each of the six vaccine manufacturers individually to discuss alternative proposals for distributing the vaccine on a voluntary basis. These meetings resulted in a mutual understanding of the problem involved and enabled the Service and the manufacturers to plan jointly a system which was acceptable to all parties concerned.

(*b*) The Secretary of the Department of Health, Education, and Welfare and the Surgeon General of the Public Health Service met with the conference of State governors to discuss the problems of equitable distribution of the vaccine, including the areas of Federal and State respon-

sibility. Following this meeting, a governors' advisory committee on Salk vaccine was appointed.

(*c*) A meeting was held with the governors' advisory committee for discussion of the plans being framed by the Department. General approval was indicated by the Committee, which agreed to poll all governors with respect to certain questions.

(*d*) Two meetings were held with the executive committee of the Association of State and Territorial Health Officers to discuss the merits of alternative plans for distribution and use of the vaccine. In these discussions, particular emphasis was given to the methodology and procedures which State health officers would follow in carrying out pertinent provisions of the plan.

(*e*) The proposed plan was discussed with the board of trustees of the American Medical Association. The association and other medical groups pledged their full support in carrying out the plan and the priority system.

(*f*) Several elements of the plan were discussed with representatives of the pharmaceutical industry as a means of determining the plan's feasibility and obtaining suggestions for its improvement, particularly with regard to those provisions affecting retail druggists.

(*g*) After development of the plan for distribution and use, it was discussed and cleared with the National Advisory Committee on Poliomyelitis Vaccine.

In all instances there was a high degree of cooperation and assistance from the groups participating in the planning.

Definition of responsibilities of Public Health Service, State agencies, and manufacturers.—Under the allocation system developed, it is the responsibility of the Federal Government to arrange for the equitable apportioning of poliomyelitis vaccine among the States—in accordance with each State's population in the current nationally recommended priority group. With the concurrence of the groups noted above, each State is allocated its proportionate share of the vaccine supply periodically cleared and released by the Public Health Service.

The essential elements of the interstate distribution plan are as follows:

(*a*) The National Advisory Committee on Poliomyelitis Vaccine from time to time recommends to the Department a specific age-priority group to receive the vaccine.

(*b*) Based on the number of persons in each State in the Federally recommended priority group, in relationship to the total number of such persons in the Nation, each State is allotted its proportionate share of each lot of vaccine released.

(*c*) Each State advises the Public Health Service of the percentage of each allotment of vaccine which should be sold to public agencies and the percentage which should be sold in regular commercial channels to druggists and physicians.

(*d*) Each manufacturer restricts the sale of vaccine to public agencies and to druggists and physicians to the percentage prescribed by each State.

(*e*) Each manufacturer provides the appropriate State health department with copies of invoices showing vaccine sold so that the State will be able to detect and secure adjustments of inequities in intrastate distribution of the vaccine.

Chart 2 illustrates the manner in which the interstate distribution plan works.

Intrastate plan for distribution of poliomyelitis vaccine

Intrastate plans.—It was obvious that the effectiveness of the vaccine distribution would depend to a large extent upon the effectiveness of plans adopted by the State to control the intrastate distribution and use of the vaccine. The Public Health Service worked with the executive committee of the Association of State and Territorial Health Officers in developing suggested principles which might be used by the State in developing intrastate controls (12).

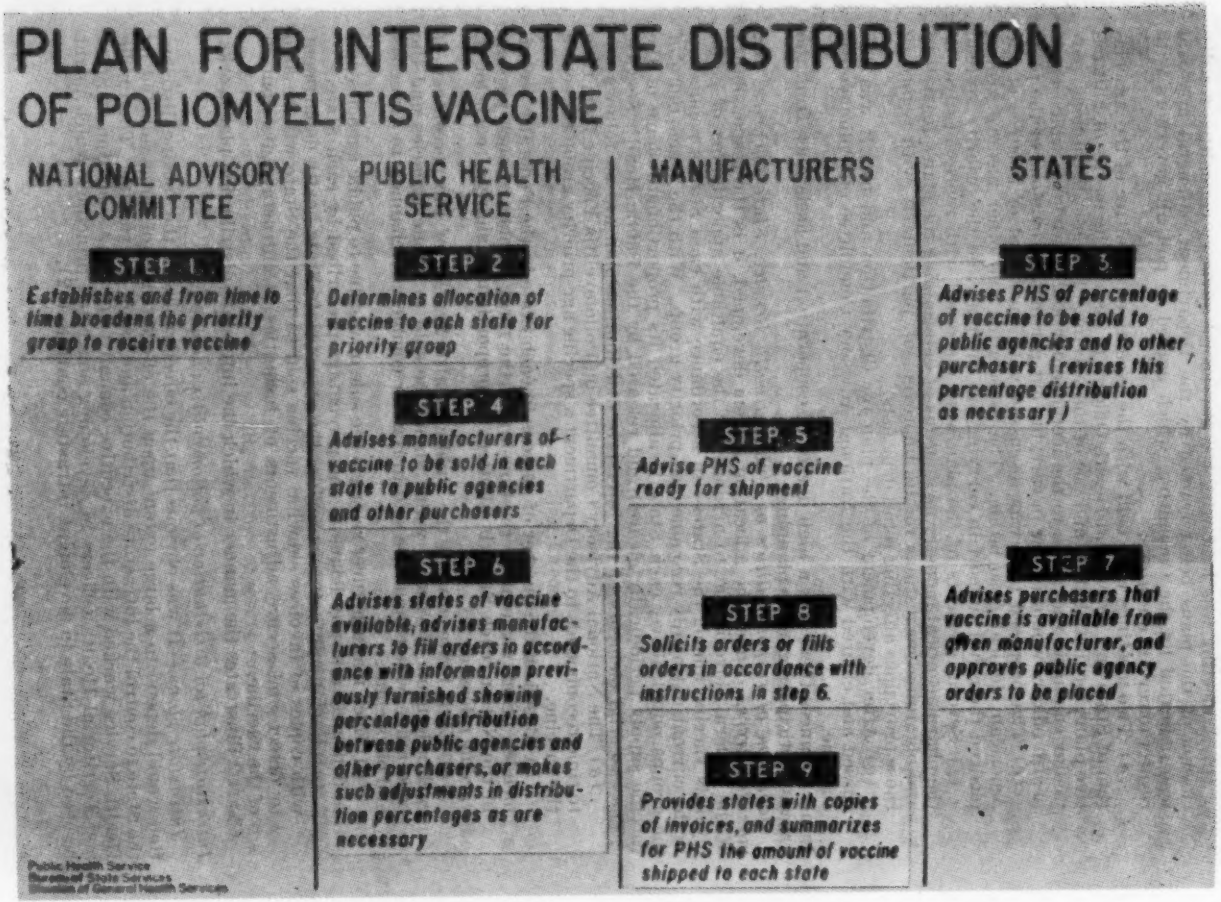
PLAN FOR INTERSTATE DISTRIBUTION
OF POLIOMYELITIS VACCINE
NATIONAL ADVISORY COMMITTEE
PUBLIC HEALTH SERVICE
MANUFACTURERS
STATES
STEP 1
Establishes and from time to time broadens the priority group to receive vaccine
STEP 2
Determines allocation of vaccine to each state for priority group
STEP 3
Advises PHS of percentage of vaccine to be sold to public agencies and to other purchasers (revises this percentage distribution as necessary)
STEP 4
Advises manufacturers of vaccine to be sold in each state to public agencies and other purchasers
STEP 5
Advise PHS of vaccine ready for shipment
STEP 6
Advises states of vaccine available, advises manufacturers to fill orders in accordance with information previously furnished showing percentage distribution between public agencies and other purchasers, or makes such adjustments in distribution percentages as are necessary
STEP 7
Advises purchasers that vaccine is available from given manufacturer, and approves public agency orders to be placed
STEP 8
Solicits orders or fills orders in accordance with instructions in step 6.
STEP 9
Provides states with copies of invoices, and summarizes for PHS the amount of vaccine shipped to each state
Public Health Service
Bureau of State Services
Division of General Health Services

CHART 2

All States except Idaho have developed plans for the intrastate control of the distribution and use of the vaccine. Because the problems of distribution and use vary from State to State, each State's plan is tailored to meet its particular requirements. A summary of the salient features of such plans is given below:

(*a*) All States and Territories, with the exception of the Canal Zone, Guam, and American Samoa, appointed an advisory committee. Although the membership of these committees varies from State to State, generally the groups most interested in the program, i. e., the medical association, public health officials, and the pharmaceutical association, are represented.

(*b*) State health agencies report that, on the whole, excellent cooperation of the medical and pharmaceutical professions has been secured.

(*c*) Allocation of vaccine within each State is based generally on the age priority group population of the local subdivisions. The amount of vaccine distributed to local subdivisions or other specific areas of the State is tabulated, and, when inequities occur, adjustments are made in allocating additional lots of publicly purchased vaccine. A number of States have also adjusted their initial allocations in accordance with demand, which varies widely from county to county. In order to meet the diverse needs, subsequent lots of vaccine are often distributed on the basis of requests rather than in proportion to the eligible population. In making these adjustments, State health agencies sometimes request that manufacturers increase or decrease the sale of vaccine in particular areas.

(*d*) Most States report that the extent to which vaccine will be administered in public clinics and by private physicians is determined at the local level—usually by the county or city health department in cooperation with the county medical society. In counties without a full-time health department, the local medical society, a special poliomyelitis committee, or other local group is utilized in cordinating the program.

(*e*) The majority of States are furnishing some free vaccine to physicians, upon request, for use in their private practice.

Priorities.—During the early months of the program—when demand for the vaccine far exceeded the supply—the National Advisory Committee recommended that its administration be restricted to children in the 5-through-9 age group (see page 19.) On a nationwide basis, this group was at greatest risk. The Federal age-group priorities are not binding upon the States so far as intrastate allocation and use of the vaccine is concerned. Nevertheless, once the vaccine had been allocated to the States on the basis of those age groups, with a few exceptions States and Territories followed the recommendation of the committee, and established as the first priority group children aged 5 through 9.

By early October 1955, the vaccine supply was approaching fulfillment of the demand for 2 injections each to the 5-through-9 age group. Almost 24 million cc. of vaccine had been released by the Public Health Service—enough to give 2 injections to three-fourths of the 16 million children in this age category. In order to expedite prompt use of the vaccine, many States had recommended to the Service that the priority group be enlarged so that vaccinations might be extended to additional ages.

On October 12, the Secretary of the Department of Health, Education, and Welfare, acting upon the unanimous recommendation of the National Advisory Committee on Poliomyelitis Vaccine, broadened the priority group to receive poliomyelitis vaccine so that it could include persons ranging from birth through 14 years of age and pregnant women.

Because the vaccine supply was still short of total demand, the Secretary further recommended that each State initially extend its priority group to embrace no more than 5 additional years of age outside the original 5-through-9 age priority group, and, if so desired, to include pregnant women. This is to enable the States to move, in an orderly way, into lower or higher age groups, according to local incidence and severity of the disease.

As a result of the differences among the States in the age groups most susceptible to poliomyelitis, the broadened priority groups adopted by the States varied

considerably. This variation is demonstrated in the following tabulation of current priority age groups:

Priority age group	*Number of States and Territories*
1 year and under:	
Through 9 years	6
Through 10 years	7
Through 14 years	26
Through 15–19 years	6
3 years: Through 12 years	2
5 years:	
Through 9 years	4
Through 14 years	2

In addition, all States and Territories except 12 include pregnant women of all ages in their priority age group.

With the broadening of the Federal priority age group, the allocation of vaccine among the States will now be based on their need for vaccine to complete the vaccination of children under 15 years of age and pregnant women. This involves an addition of approximately 36½ million persons to the priority group.

According to the State plans submitted to the Public Health Service, State health agencies and their Advisory Committees have been supported by State and local medical societies in obtaining conformance by private and clinic physicians to priority age groups established by the State. Moreover, the plans provide that physicians will maintain records of all children vaccinated. The information recorded usually includes name, address, and age of child and site and date of vaccination. In most instances, this information is filed routinely with the State health agency—either in detail, or in summary. Where data are not filed in detail they are available for spot checking by the State agency, thus providing assurance of adherence to priorities in use of the vaccine.

Immunization schedule.—On December 7, 1955, a group of leading virologists, immunologists, epidemiologists, representatives of the medical and health professions, and of the National Foundation for Infantile Paralysis discussed the possibility—during the period of short supply—of giving 1 cc. of vaccine to all individuals in the most susceptible age groups before giving any more second or booster injections. This alternative immunization schedule was considered as a possible means of giving protection to more persons during the coming poliomyelitis season. The group concluded that there was not enough scientific evidence on the duration of immunity after a single injection to support a recommendation for a change in the present immunization schedule. The Public Health Service concurred in this recommendation.

Federal assistance for purchase of vaccine

Poliomyelitis Vaccination Assistance Act of 1955.—Recognizing the importance of rapidly protecting as many children as possible from poliomyelitis, the President in April stated his belief that Federal funds should be appropriated to assist in the vaccination program. The Secretary of the Department of Health, Education, and Welfare submitted to the Congress a proposed Poliomyelitis Vaccination Assistance Act of 1955, which—with substantial amendments—was enacted. This act became law on August 12. It provided for grants to the States to be expended by February 15, 1956. Congress has appropriated $30 million to carry out the purposes of the Act. Of the total amount appropriated, $25 million is available to the States for the purchase of vaccine only. The allotment formula is based on eligible population (unvaccinated children under 20 years of age and expectant mothers) and per capita income. The remaining $5 million is available to the States for purchase of vaccine or the cost of administering the poliomyelitis vaccination distribution program. No State matching is required for either portion of the allotment. The Public Health Service may furnish vaccine in lieu of cash to a State, if the State so requests.

Applications for participation under the Poliomyelitis Vaccination Assistance Act have been submitted and approved for all States and Territories, except Massachusetts.[3] Allotments totaling $29,313,147 are available to the States and Territories having approved applications, and $7,674,776 had been certified for payment as of December 31, 1955. The disparity between allotments and payments occurs because funds are paid only as needed to purchase vaccine which has been released. Thirty-five States plan to use all or a part of their allotment of the $5 million for the purchase of vaccine.

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[3] Massachusetts, on the basis of a recent decision of its advisory committee, has now prepared a plan which will be received by the Public Health Service within a few days.

Currently, the Public Health Service is purchasing vaccine for 22 States, upon their request. As of December 31, the Public Health Service had placed purchase orders with manufacturers for 3,939,624 cc. of vaccine for these States.

Some of the salient features of applications submitted under the PVA Act are given below:

(*a*) All States agreed that vaccine purchased with Federal grant funds would be used only for the vaccination of children under the age of 20 and expectant mothers, and that records of name, age, and address of child and of place and date of vaccination would be maintained to substantiate this fact.

(*b*) In describing the methods under which vaccinations will be made available, most States indicated that they would follow the traditional patterns of providing immunizations by using regular and special clinics, school clinics, and, upon request, distributing vaccine to physicians for use in their private practice.

Of 48 States reporting on this specific item, 11 are using all publicly purchased vaccine in public clinics. Six States reported that all was being used by private physicians. In 18 States, more than 90 percent is being used in public clinics; in 23, 70 percent or more; in 31, 50 percent or more.

(*c*) As required by the act, all States and Territories agreed that no means test or other discrimination based on financial ability of individuals would be imposed to limit the eligibilty of persons to receve vaccine provided through public agency programs, regardless of the source of funds used to purchase the vaccine.

(*d*) In all States, the State health department was designated by the Governor as the single agency to administer the program.

General health funds available for poliomyelitis activities.—The "Assistance to States, general" appropriation for 1956 provided $4,500,000 to be available to the States for planning and operating a program for distribution and use of poliomyelitis vaccine. This amount was appropriated as a part of the general health grant and was earmarked exclusively for poliomyelitis activities.

Plans for distribution and use of poliomyelitis vaccine (an integral part of the applications submitted under the Poliomyelitis Vaccination Assistance Act of 1955) have been submitted and approved for all States and Territories. The total amount of $4,500,000 has been allotted to the States and Territories. As of December 31, $2,031,079 has been certified for payment.

Table 3 summarizes the current status of Federal funds appropriated for assistance to State poliomyelitis vaccination programs.

TABLE 3.—*Disposition of Federal funds appropriated for assistance to State poliomyelitis vaccination programs, fiscal year 1956*

Authority	Appropriated	Allotted	Certified for payment[1]	Balance available
Public Law 410	$4,500,000	$4,500,000	$2,031,079	$2,468,921
Public Law 377 (Poliomyelitis Vaccination Assistance Act of 1955)	30,000,000	29,313,147	7,674,776	21,638,371

[1] As of Dec. 31, 1955.

ENFORCEMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT

The Food and Drug Administration of the Department of Health, Education, and Welfare is responsible for ascertaining that poliomyelitis vaccine shipped into a State in normal drug channels remains in those channels and is sold at retail level only to licensed physicians, or on their prescriptions. This involves inspection and examination of establishments and records to obtain information regarding manufacture, transportation, wholesaling, retailing, and use of the vaccine. On the basis of this information, violations of the Federal Food, Drug, and Cosmetic Act are determined, and, where indicated, appropriate regulatory action is instituted.

In carrying out its law-enforcement program, the Food and Drug Administration has had the cooperation of industry. Manufacturers of the vaccine have furnished complete records of each batch distributed. Representative shipments have been selected for investigation on the basis of equitable coverage of each manufacturer, geographic area, and population concentration. The purpose is to determine whether the vaccine reaches the intended consignees in the invoiced quantity, and whether thereafter it is legally distributed.

To date, food and drug inspectors have visited 200 wholesale druggists, 4,900 retail pharmacies, 4,000 physicians, 400 hospitals, 100 health agencies, and 60 private homes in connection with the poliomyelitis vaccine program. Although a few instances of improper handling were discovered, there has been no problem of black marketing or illegal distribution. The Food and Drug Administration advised the Public Health Service of a few cases of possible use of vaccine outside the authorized age groups and failure to comply with the established distribution program. This information has been transmitted to the State health agencies concerned for appropriate action. Occasionally, stocks of outdated vaccine and of stocks held without refrigeration were observed. These were also reported to the health authorities.

Practically all groups involved in the distribution of poliomyelitis vaccine have indicated a desire to make certain that the vaccine remains in legitimate channels. There has been no necessity for legal action.

PART III. CURRENT STATUS OF PROGRAM

SAFETY AND EFFECTIVENESS

As explained in pages 7–13 of this report, epidemiologic observations throughout the country are providing a wealth of evidence which confirms the safety and potency of the Salk poliomyelitis vaccine. Although final data are not yet available, the reports accumulating clearly demonstrate the effectiveness of the vaccine as a preventive agent against paralytic poliomyelitis during the past season. For paralytic poliomyelitis, the rates are from 2 to more than 5 times greater among unvaccinated than among vaccinated individuals.

With respect to safety, experience with vaccine produced under the revised standards which have obtained since May 27, has been entirely satisfactory.

The Surgeon General has strongly urged that "Every available drop of the vaccine be used as expeditiously as possible by health agencies and private physicians to assure that the largest number of susceptible individuals are vaccinated before the next poliomyelitis season" (13).

SUPPLY, DISTRIBUTION, AND USE OF POLIOMYELITIS VACCINE

Supply.—One of the most acute problems in the program to date has been the difficulty of forecasting future production and release of the vaccine. The large number of tests required to insure safety of the vaccine, and the many scientific variables involved in the production and testing process, have made it impossible to estimate accurately the future production and release of vaccine. It is anticipated that early in 1956 the production and release of vaccine will become more stable, and future production will become more predictable.

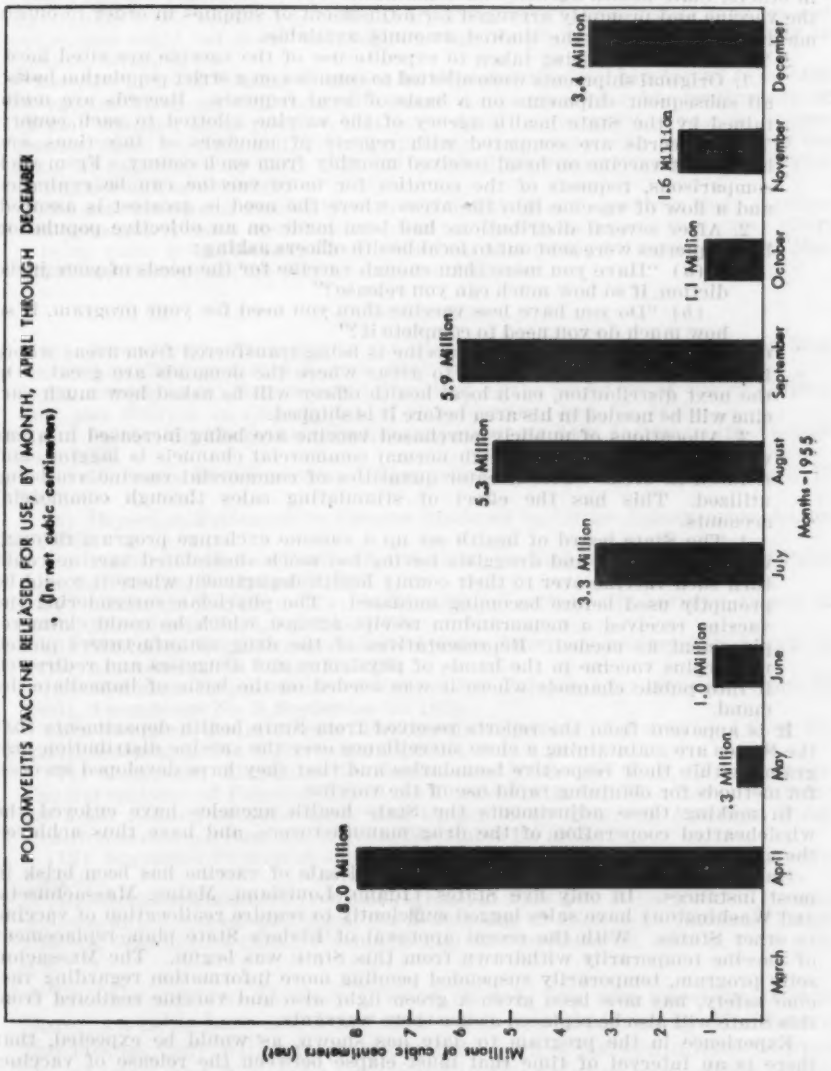
There are approximately 65 million persons in the age group 0 through 19 years or who are pregnant. To vaccinate this group of persons requires 195 million cc. of vaccine. Up to December 31, about 30 million cc. of vaccine had been released, 45 percent of which went to the National Foundation for Infantile Paralysis for immunization of first- and second-grade children.

On July 30, 1955, vaccine was released for the first time under the interstate distribution plan. During August, 5.3 million cc. of vaccine were released, and 5.9 million cc. were released during September. In October and November the quantity of vaccine released dropped sharply. In October 1.1 million cc. were released; in November 1.6 million cc. were released. (See Chart 3.) Reduction in releases during these 2 months can be attributed largely to the major changes made last May in vaccine production and testing, and to the continuing refinements since then. By December, momentum had picked up, and the amount of vaccine released rose to 3.4 million cc. It is expected that from this point on, releases will be increasingly regular and larger.

Distribution.—The mechanics of distributing vaccine on an interstate basis are now well understood by manufacturers and State health officers. As a result, this phase of the total problem presents few difficulties. The manufacturers have expressed general astisfaction with the way the distribution program has operated, and have stated that they believe all geographic areas have been given an equal opportunity to obtain vaccine.

Most State health officers have been, and are, making a determined effort to inform physicians, pharmacists, the general public and others concerned of the distribution problems within the State and the methods being followed by the

CHART 3



State in administering the program. The degree to which State health officers are successful in this regard varies from State to State, but, in the main, the informational programs of the States appear to have been effective.

Of the first lots of vaccine released to the States under the distribution plan, about two-thirds were released for sale to druggists and physicians through local distribution channels. However, as funds became available to the States under the Poliomyelitis Vaccination Assistance Act of 1955, the quantity of vaccine released for sale to public agencies has increased. At the present time, more than 60 percent of the vaccine released is being reserved for sale to public agencies.

Use.—Reports from manufacturers and State health officers reveal that, in most States, the demand for and sale of vaccine is heavy. However, because of local differences in interest, medical and public health resources, and plans of operation within the several States, there are wide local variations. In order to

prevent accumulation of excess vaccine in some areas while there is a deficiency in others, State health agencies have maintained close intelligence over usage of the vaccine and promptly arranged for adjustment of supplies in order to obtain maximum value from the limited amounts available.

A few of the steps being taken to expedite use of the vaccine are cited here:

1. Original shipments were allotted to counties on a strict population basis; all subsequent shipments on a basis of local requests. Records are maintained by the State health agency of the vaccine allotted to each county. These records are compared with reports of numbers of injections and balance of vaccine on hand received monthly from each county. From such comparisons, requests of the counties for more vaccine can be evaluated and a flow of vaccine into the areas where the need is greatest is assured.

2. After several distributions had been made on an objective population basis, queries were sent out to local health officers asking:

(*a*) "Have you more than enough vaccine for the needs of your jurisdiction, if so how much can you release?"

(*b*) "Do you have less vaccine than you need for your program, if so how much do you need to complete it?"

On the basis of these replies, vaccine is being transferred from areas where it is not currently being used to areas where the demands are great. On the next distribution, each local health officer will be asked how much vaccine will be needed in his area before it is shipped.

3. Allocations of publicly purchased vaccine are being increased in areas where sale of vaccine through normal commercial channels is lagging, and reduced in areas where greater quantities of commercial vaccine are being utilized. This has the effect of stimulating sales through commercial accounts.

4. The State board of health set up a vaccine exchange program through which physicians and druggists having too much short-dated vaccine could turn such vaccine over to their county health department where it would be promptly used before becoming outdated. The physician surrendering the vaceine received a memorandum receipt against which he could claim replacement as needed. Representatives of the drug manufacturers picked up surplus vaccine in the hands of physicians and druggists and redirected it into public channels where it was needed on the basis of immediate demand.

It is apparent from the reports received from State health departments that the States are maintaining a close surveillance over the vaccine distribution programs within their respective boundaries and that they have developed successful methods for obtaining rapid use of the vaccine.

In making these adjustments the State health agencies have enjoyed the wholehearted cooperation of the drug manufacturers, and have thus achieved the most effective use of vaccine available.

On a statewide basis, the demand for and sale of vaccine has been brisk in most instances. In only five States (Idaho, Louisiana, Maine, Massachusets, and Washington) have sales lagged sufficiently to require reallocation of vaccine to other States. With the recent approval of Idaho's State plan, replacement of vaccine temporarily withdrawn from this State was begun. The Massachusetts program, temporarily suspended pending more information regarding vaccine safety, has now been given a green light also and vaccine realloted from this State will also be replaced as use there warrants.

Experience in the program to date has shown, as would be expected, that there is an interval of time that must elapse between the release of vaccine, the shipment of vaccine, anl the use of vaccine. This interval results from a number of factors:

(*a*) Necessary time required to place orders, verify orders, and make delivery.

(*b*) Necessary time required to distribute vaccine from a central point in a State to the various localities where vaccine is to be used.

(*c*) Necessary time required to accumulate enough vaccine in a State or local community to warrant publicizing and conducting clinics.

(*d*) Necessary time required—after the amount of vaccine available in a local community is known—to schedule clinics, to publicize the clinic, to secure consent slips from parents, and to arrange for professional services.

(*e*) Retaining of vaccine locally by health officers or private physicians to insure that supplies will be available to give second injections to those children who have received their first injection.

The accumulation of sufficient quantities of vaccine to warrant scheduling of clinics and the retaining of vaccine for second injections have been of particular significance while vaccine has been in very short supply, since public agencies and physicians could not count on adequate supplies of vaccine being available to them on future dates.

Because of these factors, it cannot be expected that the number of injections of vaccine given on any date will equal the number of cubic centimeters of vaccine released or shipped on that same date. As supplies of vaccine become greater, more regular, and more predictable, it is reasonable to expect, on the basis of experience to date, that the interval between release of the vaccine and its use will be reduced.

The astuteness and flexibility with which States are operating their vaccination programs to meet specific local problems lead us to believe that every effort is being made to vaccinate as many children as possible between now and May and June, when a rush for vaccinations is anticipated.

REFERENCES

(1) Report to the President by the Secretary of Health, Education, and Welfare on Distribution of Salk Vaccine, May 16, 1955.

(2) Supplemental Report to the President by the Secretary of Health, Education, and Welfare on Distribution of Salk Vaccine, July 25, 1955.

(3) Public Health Service Technical Report on Salk Poliomyelitis Vaccine, June 1955.

(4) Minimum Requirements: Poliomyelitis Vaccine. 1st revision, April 12, 1955.

(5) Report on Poliomyelitis Vaccine Produced by Cutter Laboratories, August 25, 1955.

(6) Interim Report on Public Health Service's Technical Committee on Poliomyelitis Vaccine, November 11, 1955.

(7) Minimum Requirements: Poliomyelitis Vaccine. 1st revision (April 12, 1955), Amendment No. 1, April 19, 1955.

(8) Minimum Requirements: Poliomyelitis Vaccine. 1st revision (April 12, 1955), Amendment No. 2, May 26, 1955.

(9) Minimum Requirements: Poliomyelitis Vaccine. 1st revision (April 12, 1955), Amendment No. 3, September 10, 1955.

(10) Minimum Requirements: Poliomyelitis Vaccine. 1st revision (April 12), 1955), Amendment No. 4, November 11, 1955.

(11) Langmuir, Alexander D., Nathanson, Neal, and Hall, Wm. Jackson: The Surveillance of Poliomyelitis in the United States in 1955. Presented before the Joint Session of Laboratory and Epidemiology Sections, American Public Health Association, Kansas City, Mo., November 15, 1955.

(12) Suggested Principles of Intrastate Distribution and Use of Poliomyelitis Vaccine.

(13) Scheele, Leonard A.: A Look Ahead at Paralytic Poliomyelitis; Banquet Address at the Annual Meeting of the Association of State and Territorial Health Officers, Washington Hotel, Washington, D. C., November 10, 1955, at 7:30 p. m., e. s. t.

The CHAIRMAN. Doctor, I want to ask you one question because there is a table here and I am sure when it is observed by Members of the House, they will ask questions and I want the committee to know the answer, and it may be explained in the printed part of the report.

This is in reference to chart 3, which shows the poliomyelitis vaccine released month by month from April through December. The question in my mind is what caused the terrific drop from September, when there were 5.9 million cc.'s released, to October, when there was only 1.1 million. I am sure there is an explanation but I would like to have it for the record at this time.

Dr. SCHEELE. I am going to ask Dr. Shannon, with your permission, to answer that.

The CHAIRMAN. Dr. Shannon?

Dr. SHANNON. There always will be ups and downs on supply and in these amounts of vaccine as you see here, they are largely the result

of the operation of a single large manufacturing; that is, a single operation dominates the whole picture. What you see reflected in this total is the operation of this one manufacturer. He puts out in a single lot something on the order of 1.1 to 1.5 million cc. and when you realize that they were clearing no more than 5 or 6 million cc. per month, any slight change in the rate of his operation would immediately be reflected in the total. There is nothing other than that, sir.

The CHAIRMAN. The drop, then, would indicate a drop-off in the output of one manufacturer; is that what I understand you to say?

Dr. SHANNON. That largely dominates the picture.

The CHAIRMAN. Then I notice it begins to climb again after October, and in November and December, again it is up to 3.4 million.

Dr. SHANNON. This reflects largely what has happened to one manufacturer.

The CHAIRMAN. May I ask at this point if there have been during the past year or since the legislation was enacted last July, any particular new developments in the manufacturing processes or are any underway at the present time?

Dr. SHANNON. The main thing that has been accomplished, I will refer you first to the report of last June. At that time, largely as a result of speculation, it was believed that what was happening to cause bad batches of vaccine to come through was the clumping together or the aggregation of small virus bodies so as to remove them from contact with formalin.

It was found in the ensuing 6 months that this was, in fact, occurring. The most important thing in modifying the process was to introduce certain filtration steps so that this could not happen. This should permit straight line manufacturing to be undertaken with sizable dependence on large scale production.

The second thing is the progression of the safety techniques so that we have greater dependendability within those procedures than we had last June. But the fundamental process itself has not been modified.

More recently, certain manufacturing houses are beginning to introduce what is called supplemental inactivation.

The CHAIRMAN. I did not understand that last.

Dr. SHANNON. Supplemental inactivation; that is, doing the bulk of inactivation with formalin and then with additional ultraviolet light or chemicals or with heat. These are just now beginning to show up with the manufacturing process. But these in no way should make the vaccine better or poore, but if could well be that they will make it easier to manufacture.

The CHAIRMAN. The ultraviolet ray that you mention; is that supplemental?

Dr. SHANNON. Yes, sir.

The CHAIRMAN. Is that, so far as you know, proving effective?

Dr. SHANNON. The one manufacturer who is using that has not submitted final vaccine to us. He has it now in rather extensive tests in children in order to determine, if after the use of ultraviolet, the vaccine retains its ability to produce antibodies.

Mr. HESLETON. Mr. Chairman.

The CHAIRMAN. Yes.

Mr. HESELTON. Do I understand the chairman referred to chart 3?

The CHAIRMAN. Yes.

Mr. HESELTON. Will you straighten me out on this?

Was this just the industry distribution or does it include the amounts that were distributed through the National Foundation?

Dr. SCHEELE. This is total.

Mr. HESELTON. To both sources?

Dr. SCHEELE. Yes, sir.

Mr. HESELTON. Thank you.

The CHAIRMAN. Did you have any further comment, Doctor?

Dr. SCHEELE. I would like to add one additional explanation to Dr. Shannon's explanation of that drop in October, and it is related to the fact that one manufacturer was a large producer.

On September 10 we, under our amendment No. 3 to the regulations, or, rather, to the minimum requirements, we added a final container safety test. In other words, it became necessary then to take a certain number of bottles in which the vaccine had been placed finally and open those and pool those to test them.

That meant this large manufacturer and others had to pretty much dead halt the amount of vaccine they were able to have cleared while they did this additional test and that, in part, accounts, in a measure probably accounts, for some of this drop-down as we hit in October and November.

The CHAIRMAN. Doctor, in that final container test, let us say, how many cubic centimeters out of a thousand, let us just use that as a ratio, about how many cubic centimeters out of a thousand would be subject to that final container test?

Dr. SHANNON. It is not a proportion of the total, but out of each filling lot. Let me read it here. At least 100 milliliters of each filling lot. In other words, the manufacturing lot may be made up of a number of filling lots, a filling lot being a distinct manufacturing step. One hundred milliliters of that would be tested.

More recently, this test has been again modified so as to put the Cortisone monkey in at the end as the final container test. In those instances, each test will include 18 monkeys that will get approximately 2 or 3 milliliters of vaccine.

The first is the tissue culture test and the second is the monkey test.

The CHAIRMAN. Thank you, Dr. Shannon.

Mr. Springer, do you have any questions?

Mr. SPRINGER. Just two questions.

Dr. Scheele, you were present at all those hearings we had last June, were you not?

Dr. SCHEELE. That is right.

Mr. SPRINGER. Do you recall during all those hearings I maintained that you were on the right track, and I think the hearings there backed you up. I think you have done a marvelous job and I want to say that for you and your department.

You recall possibly one sentence I used at that time was that the proof was in the pudding. Now, at page 3 of your statement, you make these statements:

Experience during 1955 has shown that the paralytic poliomyelitis rate was more than four times greater among unvaccinated children than it was among vaccinated children in the same age group and same locality.

that is the proof?

Dr. SCHEELE. Yes, sir.

Mr. SPRINGER. That is, in 1955, in spite of the fact that the greater majority of children that received shots received not 3 shots but 1?

Dr. SCHEELE. That is correct.

Mr. SPRINGER. Just one further question, Doctor.

Do you believe that the amount of money which was allotted under the bill last year is sufficient to carry this job through to conclusion by June 30, 1957?

Dr. SCHEELE. The amount of money which is implied in the formula, which is approximately $60 million, plus or minus, depending on the cost of the vaccine, is, in our opinion, enough to carry what would be an appropriate Federal share of the load in terms of grants to the States for vaccine and for giving of the vaccine.

Yes, sir; we believe that.

Mr. SPRINGER. Your experimentation in this whole field, as I understand it, in improving the effectiveness of this vaccine, is a continuing project, is it not?

Dr. SCHEELE. Yes, sir; it is.

Mr. SPRINGER. And you do not now see any conclusion to those experiments at this time, do you?

Dr. SCHEELE. No, sir. This is true of all medicine. It is in constant research and we are constantly trying to improve. This is such a continuous process that normally it goes unrecognized. It happens in the case of polio vaccine, it happens to have been something that everyone was interested in and, in this instance, the American public at large has been able very nicely to watch the changes.

Mr. SPRINGER. In other words, at the present time you have not reached a position in the experimentation field that you believe you have a vaccine that is equal, we will say, to the one you now have smallpox or for any other related disease?

Dr. SCHEELE. It may be very difficult to give a scientific comparison between this vaccine and that for smallpox.

Dr. Langmuir is an expert epidemiologist; perhaps he would like to comment.

Dr. LANGMUIR. I would like to make two points on that: One is that there is a sphere for improvement of smallpox vaccine in spite of the fact that it is 150 years old, the latest being that of making it in dried form so it can be used more practically in the Tropics.

For polio vaccine, there is a wide-open field, it seems to me, for years to come and only time will tell us whether the present product is practical and good to achieve the objective of eradication of the disease. Many of us are quite hopeful that this is a good enough product to go a long way toward that, but certainly it can be improved in many ways.

Mr. SPRINGER. Are you talking about poliomyelitis now?

Dr. LANGMUIR. Yes.

Mr. SPRINGER. And smallpox, too?

Dr. LANGMUIR. It is still a continuing program. We have to maintain our immunity to smallpox or epidemics will return. The most effective vaccine for smallpox I am sure could be improved.

Dr. SCHEELE. It should be pointed out that on polio vaccine, not only are efforts being made to improve the vaccine by substituting another strain at some future time if possible for the Mahoney, but the National Foundation for Infantile Paralysis is supporting extensive research in different types of vaccine. This is what is called, in the vernacular,

a killed virus vaccine and they are supporting work being done by several groups on an attenuated so-called live virus vaccine.

Mr. SPRINGER. The line of questioning that Mr. Heselton submitted to you a while ago, I take it you are satisfied with the rate of improvement that you are having as a result of your experimentation?

Dr. SCHEELE. Yes, sir.

Mr. SPRINGER. That is all.

The CHAIRMAN. Mr. Hayworth.

Mr. HAYWORTH. No questions.

The CHAIRMAN. Dr. Scheele, and all of your associates and assistants, we thank you very much for your appearance here today, for the report you have given us, and for the manner in which you have attempted to answer all of our questions.

I think we all realize that there are still questions which all of us seek the answer for; that those questions may not all be answered at this time, but tomorrow, next day or next year or later yet, we may find more and more of the answers.

We deeply appreciate your appearance and I want to join my colleague, Mr. Heselton, in expressing my personal opinion that with this program as conducted since the legislation was passed last year, the department and the States working together have done a very remarkable job.

We thank you, sir.

Dr. SCHEELE. Thank you, gentlemen.

The CHAIRMAN. Our next witness will be Dr. Bergsma.

Dr. Bergsma was a member of our panel last year and contributed greatly to the discussion of that panel. He is president of the Association of State and Territorial Health Officers and is also commissioner of health for the State of New Jersey.

We are happy to welcome you again before the committee, Doctor.

STATEMENT OF DR. DANIEL BERGSMA, PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS, AND COMMISSIONER OF HEALTH, STATE OF NEW JERSEY, STATEHOUSE, TRENTON, N. J.

Dr. BERGSMA. Thank you, sir.

I would like to make a very brief statement as the president of the Association of State and Territorial Health Officers.

Mr. Chairman and members of the committee, I am pleased to have this opportunity to appear before you.

The Association of State and Territorial Health Officers, representing the administrative State health officers of the 48 States, Alaska, Hawaii, Puerto Rico, and the Virgin Islands, respectfully urges that the Congress amend sections 2 and 6 of the Poliomyelitis Vaccination Assistance Act of 1955, Public Law 377 of the 84th Congress, so as to extend the time limitations for availability and expenditure of funds thereunder.

As president of the Association of State and Territorial Health Officers, I wish to report that either the Hill-Smith bill, S. 2990, or the Priest bill, H. R. 8704, would adequately effect the above recommendation of this association and we respectfully urge the passage of H. R. 8704 or S. 2990 before February 15, 1956, to assure efficient administration and continuity of this program.

The association further respectfully urges that the Congress appropriate, by subsequent legislation, such additional sums as may be needful to fully accomplish the purpose of Public Law 377 of the 84th Congress.

The CHAIRMAN. Doctor, in your suggestion for an extension of the date, you mean an extension of the date beyond that recommended by the department of June 30, 1957?

Dr. BERGSMA. No, sir; that date would seem good to us.

The CHAIRMAN. Well, I must have misunderstood your statement there because I was under the impression that it was the date, the final expiration date, that you were concerned about.

Dr. BERGSMA. It was in terms of current legislation that exists. The current legislation that exists, has a terminal date as I understand it of February 15, 1956.

The CHAIRMAN. Yes.

Dr. BERGSMA. We concur heartily in the proposed date of June 30, 1957, as given in either of the two bills referred to.

The CHAIRMAN. May I ask you this question:

Insofar as the State and Territorial health officers are concerned, the law with the date changed to June 30, 1957, would be adequate in your opinion?

Dr. BERGSMA. It would be adequate for the immediate future.

It is our opinion, sir, that the appropriation made to date would not be adequate to carry out the purposes of the bill that exists as law at the moment.

The CHAIRMAN. May I say that that is also my own opinion and I gathered from Dr. Scheele's testimony this morning that the Department proposed to ask for a supplemental appropriation.

You were here, I believe?

Dr. BERGSMA. Yes, sir.

The CHAIRMAN. That would run around $30 million, I believe he estimated.

In your opinion, would that supplemental appropriation, plus what we have already appropriated, be adequate to carry out the provisions of the act until that June expiration date?

Dr. BERGSMA. I do think it would, sir. On the basis of all information available to me, that is a very close estimate.

The CHAIRMAN. I share your opinion that an additional appropriation will be necessary to carry out the intention of the act if we extend it to June 30, 1957.

Are there any other questions of Dr. Bergsma?

Mr. HESELTON. Mr. Chairman?

The CHAIRMAN. Mr. Heselton.

Mr. HESELTON. Doctor, I found one sentence in the message of our former colleague who is now Governor of Massachusetts, Governor Herter, to the legislature last Wednesday in Massachusetts, which I had not found time before to read completely.

I was discussing this problem with Dr. Scheele and I wanted your opinion on the subject matter.

May I read that?

I am advised that the priority established by the Federal Government for children under 14 and pregnant women was established because these are the most susceptible individuals, but persons aged 15 to 19 also run a substantial

risk and that, unhappily, if they should become infected, they are hit harder than the younger group.

He goes on to say that if the priorities are relaxed, he will make further recommendations to the legislature.

The point I would like to have your opinion on, both as head of the association and as a doctor, a competent professional person, who has testified before this committee, is:

Do you believe that the committee or someone should give some attention to this slightly older age group, which apparently has, at least in the most recent experience I have known anything about, suffered quite as much as and perhaps in some instances more than some of the groups that now have priorities?

Dr. BERGSMA. The information that I have studied, sir agrees with that concept to this extent: that, individually, persons who are older than 15 who actually get paralytic polio are more apt to have a more severe case of paralysis than another single individual who is under 15 at the time he develops paralytic poliomyelitis.

However, on the basis of equal numbers of people, and in terms of groups of people, there will be so many fewer individuals in the older age group actually acquiring poliomyelitis with paralysis that the combined number of persons in the 15 through 19 group, for example, who would develop paralytic polio would be so much less than a group, say, 5 through 9, that the combined amount of human misery is less even though, in terms of a given individual, it might be more.

Does that make it clearer or less clear?

Mr. HESELTON. I have great respect for anything you say.

My own impression from reading the study in Massachusetts was that that group suffered as much bulbar polio and paralytic polio as did any group until you got down to approximately the 10-year-old group. If that is so, why, it would be an important thing to provide as much protection for that group.

It may be that the 4- or 5-year-old group and the nineteens and twenties suffer most. Some attention should be given to them, hoping that, overall, everybody will receive benefits, but some attention should be given to those hit hardest.

Dr. BERGSMA. May I add this, sir?

The persons, and there are many who are concerned with this problem, a great deal of thought has been given to it—the pros and cons I guess have been fairly exhaustively considered. The unfortunate fact is that in a single localized epidemic it could be that a 15- to 19-year-old group was definitely hit hardest, but no one can foretell that that will be the experience in any given epidemic.

Furthermore, no one can foretell exactly where such a localized epidemic will strike, and therefore we are forced to deal with the overall experience and get back to averages.

In an attempt to clarify this with a bar graph in addition to the words, may I show this to you gentlemen?

This is a bar graph which was prepared from records collected and analyzed by the National Foundation for Infantile Paralysis. It represents acute polio admissions to hospitals. They represent the more serious cases.

Acute polio admissions to hospitals per 100,000 population, with an onset between these two dates which I think are unimportant for our purpose. You will note they are broken down by age bands.

The first bar represents in the light gray the year 1954 and the dark bar in each case, the solid black bar, represents the experience in 1955.

The first bar in gray is under 5, the children under 5.

You will note in the year 1955 there were less cases hospitalized than in 1954. The 5-year age as a single year was definitely higher in both instances. In the sixth year it was again a little higher in 1954 but a little lower in 1955.

Those fluctuations are normal biological phenomena.

You will note in the age band of 7 years, for the year 1954 the level was almost as high as for the 5- and 6-year groups, and similarly with the 8-year band.

You will note that it consistently went down from that point on until here you have rates which cover the bands from 10 through 14, 15 through 19, which is definitely less, and then 20–24, 25–29, and this is the group 30 and over. So that, even in the group 30 and over, there are serious cases of polio which occur which need hospitalization, but the trend throughout the country, the overall picture, is very consistent and it is consistent not only for 1 year, but for successive years.

This chart actually shows something else which I think is extremely important in terms of the question of the safety of the vaccine that has been used. If the vaccine in general had been a serious source of causing new cases of polio, then these children in the 7-year band and the 8-year band who got practically all of the vaccine in 1955 and early 1955 should have had higher rates because, in addition to the attack from nature, there then would have been the attack from this vaccine. But the reverse is what happened.

You will note that for those 2 years the black columns are much lower, and then in the 9-year group it goes back up to about where you would have expected it to be had there been no other factor in the environment.

So I feel, sir, that this chart shows two things rather clearly. One is that this age band, 5 through 9, does on an overall basis, represent the group that really are subjected to the greatest hazard, and, therefore, ideally should be given the first protection that is available and given all that is available until the supply is increased.

The other things that I think this chart shows very clearly is that this vaccine did protect many individuals who got it because here is the proof, the number of children countrywide who ended up in hospitals because of acute polio admissions were way down in only those two age groups where most of the vaccine was given in 1954 and early 1955.

Mr. HESELTON. From what year to what year are those?

Dr. BERGSMA. This represents the people who had acute polio admissions to hospitals with onsets of disease from June 26 through September 17 of 1955, and also from June 20 to September 10, 1954.

Mr. HESELTON. I am glad you have given that.

What I meant was: From what age to what age?

I take it that the age starts at a low age at the left and goes to the right?

Dr. BERGSMA. That is right.

The first column covers all admissions with ages under 5.

Mr. HESELTON. What is the last column to the right?

Dr. BERGSMA. Thirty years and over. They are expressed as rates per hundred thousand.

Mr. HESELTON. Did you say that the evidence which is the basis of the chart shows that there was a higher incidence and higher likelihood of paralytic results or serious results in the age group of 5 to 9?

Dr. BERGSMA. Yes, sir.

Mr. HESELTON. The priority that we have established under the law is up to 14, is it not?

Dr. BERGSMA. I think that the existing law permits all those under 20, plus pregnant women, to receive it.

Mr. HESELTON. That, then, is subject to the State plan?

Dr. BERGSMA. Yes, sir.

Mr. HESELTON. And they vary to some degree?

Dr. BERGSMA. Yes, sir.

Mr. HESELTON. But if you go above 20, because of the limitations on production there is no vaccine available to people above that age; am I right?

Dr. BERGSMA. That is right.

May I add that our experience in New Jersey up until now is that we have supplied 199,498 cc. to public clinics, to municipalities who wish to run public clinics, and that data goes through January 16, 1956.

We have at this moment on hand request from municipalities for 172,073 cc.'s more and in every case those are only for the very first injection.

In New Jersey our age band at the moment for eligibles is those 14 years and under, plus pregnant women. So, without adding any additional potential eligibles, we cannot meet the current demand.

Mr. HESELTON. Do you have substantial requests for vaccination on the part of people who are over 19?

Dr. BERGSMA. Well, they know from our publication of the State regulation with the Secretary of State and the publicity it has gotten and the information that has gone out in the press at various times that those are the people who are eligible and we have expressly asked parents not to plead with physicians and others for vaccine for persons who are not in that age bracket.

It so happens I had an experience much as was recited today.

I have 2 children and by the regulation which I helped to make, 1 is eligible and 1 is not. He thinks I ought to be able to make a better rule than that.

Frankly, I firmly believe that that is the best way to do the most good for the greatest number.

Mr. HESELTON. What I am trying to get for the record is, Do you in New Jersey have these requests from people who are not eligible in the face of the fact that they generally know they cannot get it?

Dr. BERGSMA. Specific requests have not come to my attention except in a few rare instances but I am sure that there is a great desire for it among some older people.

Mr. HESELTON. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Hayworth?

Mr. HAYWORTH. Dr. Bergsma, you mentioned a few moments ago that you thought the amount of $30 million would be appropriate for supplemental appropriations and you said that that was based on your observation. I realize that that will come up at a later time, more appropriate time.

However, looking forward to that time, I wonder if you would tell us what kind of thinking or what kind of observation that is based upon?

Dr. BERGSMA. First, it is more or less the simple mathematics of the fact that the current Federal law as I interpret it makes only one-third of all the eligible persons, or rather one-third of all the persons in this 48 States plus the Territories eligible to receive it because the funds are being allocated on that base.

It is one-third of that population times a formula which simply gives a little greater share to the less wealthy States and a smaller share to the more wealthy ones.

It is clear, it seems to me, that under 21 plus pregnant women, if you use that alone and use it times the cost of the current vaccine, I think you will find that it will cost approximately a total of $60 million. That was the base for my statement.

I do know, at least I am personally convinced, that as a result of the clause referred to earlier today in the Federal statute, that if a public clinic is conducted, that no means test may be applied, I feel quite sure that there are as a result of that rule and that operation certain people who would not have been eligible if a rigid means test had been applied, to be sure that it was only the correct given percentage in a given State in the economic level that were given the vaccine.

I am also convinced that not every child who by the other part of the law would be eligible in fact get it. Some parents will not permit their children to be vaccinated, regardless of the fact that they could have gotten it free. I think that will balance it out.

If there is a difference I, at this point, could not express it in dollars, and that is why I said I thought that figure was very reasonable.

Mr. HAYWORTH. How do you in New Jersey decide who will get the vaccine?

Dr. BERGSMA. In public clinics, anyone who comes to the public clinic and wants it may have it, provided they are under 15 years of age or pregnant.

In the case of those who go to a physician's office, they again must be within those age bands or pregnant in order to be eligible to receive it. They decide for themselves where they will go, with this one exception, that we have 567 different municipalities in New Jersey and not every municipality has decided to conduct a public clinic. Therefore, a citizen who lives in a municipality that did not decide to run a public clinic obviously must elect the other alternative, namely, to go to a physician's office to receive the vaccine unless, and this is true in some cases, where they could go to a nearby municipality that was conducting a clinic and they had no objection to a person who was a nonresident getting the vaccine at this clinic.

Mr. HAYWORTH. Thank you.

The CHAIRMAN. Any further questions?

Dr. Bergsma, as president of the State and Territorial Health Officers Association, and I am sure fully familiar with all that has gone on, would you say that the program under this act up to date in the States has been generally satisfacory?

Dr. BERGSMA. That is my understanding of it; yes, sir.

The CHAIRMAN. You have not had any adverse reports of any serious character?

Dr. BERGSMA. I would not consider them serious.

The CHAIRMAN. It has been my impression, and I have tried to keep with it as best I could during the interim, knowing that we had to take a second look at it in this session, that it has been a very successful program.

I am more familiar with my own State than any other State, but I have been in close touch with Dr. Hutchinson, the Health Commissioner, and others, and on the basis of the information they have given me, I feel quite convinced that the program has moved rather satisfactorily.

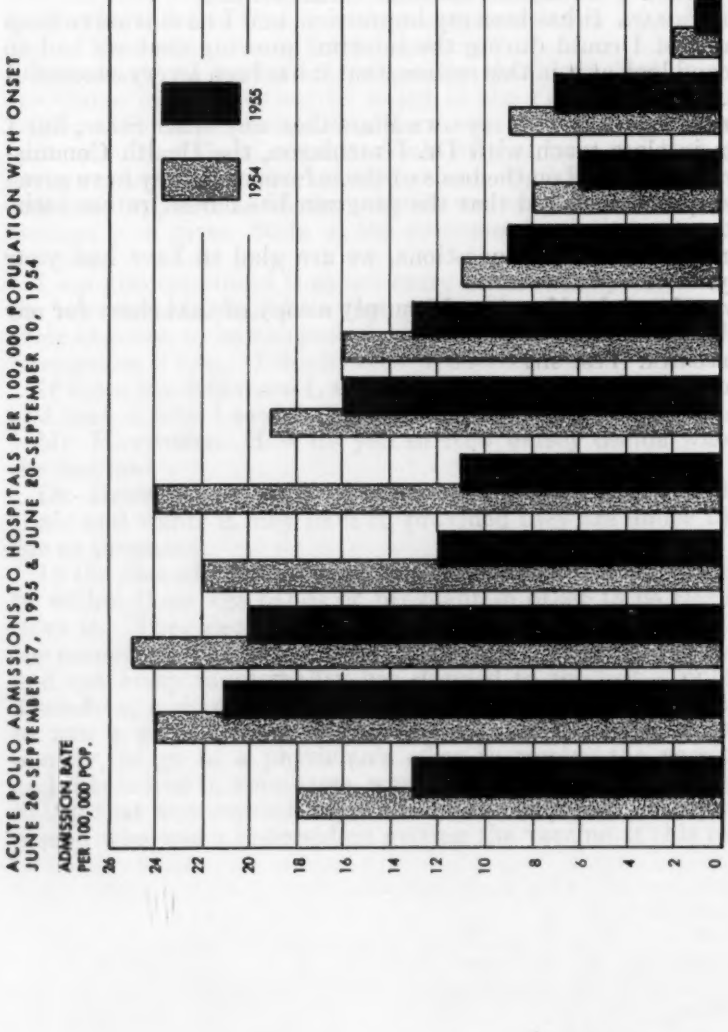
If there are no further questions, we are glad to have had your testimony.

However, I wonder if you could supply a copy of that chart for our record?

Dr. BERGSMA. Yes, sir.

(The chart referred to follows:)

CHART 4



Prepared from records collected and analyzed by the National Foundation for Infantile Paralysis.

The CHAIRMAN. Mr. Overbeck.

May the Chair state, and I hope the witness will understand the position of the Chair in this matter, you requested to be heard by this subcommittee and the committee is always tolerant of all requests.

In looking over your prepared statement, I find very little in it that deals in any manner with the question before the committee and that is the extension of the Poliomyelitis Vaccination Act of 1954.

It appears to the Chair that most of your statement deals with the question of foods and if before any committee, properly should be before the Agriculture Committee.

However, since you received a notice and had asked to be heard, the Chair is willing to hear you for 5 minutes.

STATEMENT OF JOHN OVERBECK

Mr. OVERBECK. Thank you for this time. This is more time than I am usually given because we have reached a stage in this country that in all of our health agencies food is ignored, and that is what we are made of.

For instance, when I go into the schools now the food is not a part of the program to promote health among the children. For instance, the people who have charge of the feeding of the children in our schools use bread of that type made from stoneground flour without any chemicals or drugs added. But when we feed our children in our schools, then we use this kind of stuff with clay from the West Virginia hills, and about 65 chemicals used in it.

I go to the home of Secretary of Agriculture, Mr. Benson, and this is what we find them using in their home: Wheat, rice, oats, barley. Those are not permitted to be used in our schools, believe it or not. Those are not recommended for our schools.

I bet we have our reporters just filling up their sheets with it. This is something that we ignored.

I asked a man: "Why is it that in India they have practically no polio?" He had been there for 40 years and did not know where to find a case of it.

He said, "There seems to be something about wheat and oats and barley and rice that they use there that provides antibodies."

I said, "Why don't they use it in this country in our schools?"

He said, "Heck, there wouldn't be any polio."

Believe it or not.

Here is a report from the State of North Carolina. Dr. Sandler, the head of the Veterans' hospital at Oteen, was very succesful in getting rid of TB and polio in the hospital there among the servicemen and their families. They invited him to put on a program in their State where they had 3,000 cases of polio.

He taught them to get away from the white foods. You see, polio begins when we start refining our wheat, sugar, our oats and various grains so that they will keep and be shipped to the end of the world without spoilage. He taught them to get away from white rice and so forth.

Polio went from 2,840 down to 202. I am sorry to say that he was fired for that job. He wrote three letters to the polio foundation and not one of them is answered, he told me.

This is a report that he has on that. Even the city of Asheville, which had 75 cases of polio the year that he started, was cut down to 5.

I have found the same thing in other territories of the United States. I was in the school systems in Arkansas where polio was very, very prevalent. Some schools there were having 3 to 5 cases a week in 1 school. In one place they had laid off the dietician who was using these foods. They had a couple go out to buy meat and grains and they use that for the children. Polio disappeared within a very short time and that man took the prize as having the best health record of any school in the State.

The State of Iowa, I understand, uses the same record as North Carolina, but I have not been able to get records because it is very difficult to get any program. That is the reason that when I go before a group like this, 5 minutes is the maximum.

I went before the Health Education Forum and they said 3 minutes, and also they told me that food had nothing to do with mental diseases, and they are curing the worst forms of insanity with proper food.

They can take a group of men and women in straitjackets, very vicious, criminally insance, and with proper food they can be cured. Natural grains are the basic foods of our civilization. They are basic foods, the Bible tells us, the staff of life. Ninety percent of them can be taken home to their families in 60 days' time.

You are appropriating for polio. First, appropriate some funds to send people out to teach these dieticians.

In the Department of Agriculture in the south end of the building, you have the Food and Drug Administration warning the people of the Nation that we have 801 chemicals in our food and only 206 are approved.

In the same building is the Home Economics Department, where they recommend all these drugs in our food and girls in the Home Economics Department use that kind of bread for their homes.

The man who has charge of the school-lunch program uses that in his home, and also these natural grains after his own child was stricken with polio and rheumatic fever.

In the county nearby here, the county officer shot his own child with Salk vaccine and the child came down with polio. He still recommends the program when polio could be eliminated from any community by stopping the use of these refined foods and these drugs.

You do not need to appropriate any money for shots because they are absolutely not needed if you will just change the foods in any community.

Overseas there is practically no polio in Russia because they use the black bread. They have practically no call for them there.

In Africa I talked to some doctors and after 11 years in 7 hospitals there, they said they could not recall 1 case of polio, 1 case of cancer, 1 case of heart trouble. Those cases start when we start making this kind of food.

The CHAIRMAN. You have proceeded now for 6 minutes.

We thank you very much for your interest in the subject.

Mr. OVERBECK. Whenever you feel as though this is important, I will be glad to come back.

The CHAIRMAN. Thank you, sir.

Are there any questions?

The committee will stand adjourned.

(The following communication was submitted for the record:)

GROUP HEALTH ASSOCIATION, INC.,
Washington, D. C., January 26, 1956.

The Cooperative Health Federation of America is concerned about the total health of the American people. From this point of view we believe the Salk vaccine has been proven to be effective in preventing polio and that therefore it should be the aim of Congress and of all legislation to expedite in every proper way the vaccination of all children in our country at the earliest possible date. If public funds are necessary to accomplish this result—and we believe they are—then no better expenditure could be made, and no better contribution to the strength and welfare of our Nation.

Since this subject does not lie in the field of CHFA's special competence, we do not presume to tell the Congress exactly how the program should be carried out. We do believe however that vaccination should proceed at a more rapid rate than heretofore.

DILLON S. MYER, *Executive Director.*

(Whereupon, at 3:45 p. m., the subcommittee recessed, subject to the call of the Chair.)